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Rules and Regulations

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The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

DEPARTMENT OF AGRICULTURE

Office of the Secretary

7 CFR Part 2

RIN 0503–AA59

Designation of First Assistants

AGENCY: Office of the Secretary, USDA.

ACTION: Final rule.

SUMMARY: This document amends the existing delegations of authority to provide for the designation of First Assistants to positions to which appointment is required to be made by the President with the advice and consent of the Senate.

DATES: Effective July 15, 2016.

FOR FURTHER INFORMATION CONTACT: Melissa McClellan, Office of the General Counsel, USDA, 3311-South Bldg., 1400 Independence Avenue SW., Washington, DC 20250, (202) 720–9425, *melissa.mcclellan@usda.gov.*

SUPPLEMENTARY INFORMATION: Section 3345 of title 5, United States Code, provides that when an officer of an Executive agency whose appointment is required to be made by the President with the advice and consent of the Senate dies, resigns, or is otherwise unable to perform the functions and duties of the office, the first assistant to the office of such officer (''First Assistant'') may perform temporarily the functions and duties of the office in an acting capacity. This rule authorizes the Secretary to establish a First Assistant to each office within the Department of Agriculture to which appointment is required to be made by the President with the advice and consent of the Senate (''PAS office'').

If there is a principal deputy position to the PAS office, the principal deputy position is the First Assistant. If there is no position with the title ''principal deputy,'' but there is one, and only one, deputy position to the PAS office, that deputy position is the First Assistant. If there is more than one deputy position to the PAS office, and the delegations of authority by the Secretary published in part 2 of title 7 of the CFR establish which deputy has the authority to perform all the duties and exercise all the powers of the PAS office, then that deputy delegated such authority is the First Assistant.

If there is no position or deputy that qualifies as a First Assistant under these tests, then the Secretary may designate in writing a First Assistant position to the PAS office, with the exception of the Inspector General.

Classification

This rule relates to internal agency management. Accordingly, pursuant to 5 U.S.C. 553, notice of proposed rulemaking and opportunity for comment are not required, and this rule may be made effective less than 30 days after publication in the **Federal Register.** This rule also is exempt from the provisions of Executive Order 12866. This action is not a rule as defined by the Regulatory Flexibility Act, as amended by the Small Business Regulatory Enforcement Fairness Act of 1996, 5 U.S.C. 601 *et seq.,* or the Congressional Review Act, 5 U.S.C. 801 *et seq.,* and thus is exempt from the provisions of those acts. This rule contains no information collection or recordkeeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

List of Subjects in 7 CFR Part 2

Authority delegations (Government agencies).

Accordingly, 7 CFR part 2 is amended as follows:

PART 2—DELEGATIONS OF AUTHORITY BY THE SECRETARY OF AGRICULTURE AND GENERAL OFFICERS OF THE DEPARTMENT

■ 1. The authority citation for part 2 continues to read as follows:

Authority: 7 U.S.C. 6912(a)(1); 5 U.S.C. 301; Reorganization Plan No. 2 of 1953, 3 CFR 1949–1953 Comp., p. 1024.

■ 2. Add § 2.6 to subpart B to read as follows:

§ 2.6 Designation of first assistants.

(a) Every office within the Department to which appointment is required to be made by the President with the advice and consent of the Senate (''PAS Office'') may have a First Assistant within the meaning of 5 U.S.C. 3345–3349d.

(1) Where there is a position of principal deputy to the PAS Office, the principal deputy shall be the First Assistant.

(2) Where there is only one deputy position to the PAS Office, the official in that position shall be the First Assistant.

(3) Where there is more than one deputy position to the PAS Office, and this part establishes which deputy is delegated the authority to perform all the duties and exercise all the powers of the PAS Office during the absence or unavailability of the PAS official, the deputy delegated such authority shall be the First Assistant.

(4) Where neither paragraph (a)(1), (2), nor (3) of this section is applicable to the PAS Office, except as provided in paragraph (b) of this section, the Secretary may designate in writing the First Assistant position.

(b) The Inspector General of the Department shall determine any arrangements for the temporary performance of the functions and duties of the Inspector General when that office is vacant.

Thomas J. Vilsack,
Secretary of Agriculture.

[FR Doc. 2016–16599 Filed 7–14–16; 8:45 am]

BILLING CODE 3410–90–P

NUCLEAR REGULATORY COMMISSION

10 CFR Part 171

[NRC–2008–0664]

RIN 3150–AI54

Variable Annual Fee Structure for Small Modular Reactors; Corrections

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule; correcting amendments.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) published a final rule in the **Federal Register** on May 24, 2016, amending its licensing, inspection, and annual fee regulations to establish a variable annual fee

structure for light-water small modular reactors. The final rule contained a grammatical error in a definition, an incorrect reference format, and an incomplete signature date. This document corrects the final rule by revising the sections that contain these errors and completing the signature date.

DATES: This rule is effective on July 15, 2016.

ADDRESSES: Please refer to Docket ID NRC–2008–0664 when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document using any of the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2008–0664. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select "*ADAMS Public Documents*" and then select "*Begin Web-based ADAMS Search.*" For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced in this document (if that document is available in ADAMS) is provided the first time that a document is referenced.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Michele Kaplan, Office of the Chief Financial Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone: 301–415–5256, email: *Michele.Kaplan@nrc.gov.*

SUPPLEMENTARY INFORMATION: The NRC published a final rule in the **Federal Register** on May 24, 2016 (81 FR 32617), effective June 23, 2016, amending its licensing, inspection, and annual fee regulations in parts 170 and 171 of title 10 of the *Code of Federal Regulations* to establish a variable annual fee structure for light-water small modular reactors. The final rule contained a grammatical error in the definition of *variable rate* that was added to § 171.5, "Definitions," and an incorrect reference format in a paragraph that was added to § 171.15, "Annual fees: Reactor licenses and independent spent fuel storage licenses." The final rule also included an incomplete signature date for the rule. This document corrects the final rule by revising the definition for variable rate, revising the reference format in § 171.15(e)(1), and correcting the signature date for the final rule.

Rulemaking Procedure

Under the Administrative Procedure Act (5 U.S.C. 553(b)), an agency may waive the normal notice and comment requirements if it finds, for good cause, that they are impracticable, unnecessary, or contrary to the public interest. As authorized by 5 U.S.C. 553(b)(3)(B), the NRC finds good cause to waive notice and opportunity for comment on the amendments because they will have no substantive impact and are of a minor and administrative nature dealing with corrections to certain CFR sections related only to management, organization, procedure, and practice. Specifically, these amendments are to correct grammatical errors and to revise cross-references to comply with the Office of the Federal Register's Document Drafting Handbook. These amendments do not require action by any person or entity regulated by the NRC. Also, the final rule does not change the substantive responsibilities of any person or entity regulated by the NRC. Furthermore, for the reasons stated above, the NRC finds, pursuant to 5 U.S.C. 553(d)(3), that good cause exists to make this rule effective upon publication of this notice.

Correction to the Signature Date

In FR Doc. 2016–11975 appearing on page 32617 in the **Federal Register** of Tuesday, May 24, 2016, the following correction to the signature date is made:

1. On page 32628, in the first column, the signature date is corrected to read as follows: Dated at Rockville, Maryland, this 6th day of May, 2016.

List of Subjects in 10 CFR Part 171

Annual charges, Byproduct material, Holders of certificates, registrations, approvals, Intergovernmental relations, Nonpayment penalties, Nuclear materials, Nuclear power plants and reactors, Source material, Special nuclear material.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 552 and 553, the NRC is adopting the following correcting amendments to 10 CFR part 171:

PART 171—ANNUAL FEES FOR REACTOR LICENSES AND FUEL CYCLE LICENSES AND MATERIALS LICENSES, INCLUDING HOLDERS OF CERTIFICATES OF COMPLIANCE, REGISTRATIONS, AND QUALITY ASSURANCE PROGRAM APPROVALS AND GOVERNMENT AGENCIES LICENSED BY THE NRC

■ 1. The authority citation for part 171 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 11, 161(w), 223, 234 (42 U.S.C. 2014, 2201(w), 2273, 2282); Energy Reorganization Act of 1974, sec. 201 (42 U.S.C. 5841); 42 U.S.C. 2214; 44 U.S.C. 3504 note.

■ 2. In § 171.5, revise the definition of *variable rate* to read as follows:

§ 171.5 Definitions.

* * * * *

Variable rate means a per-MWt fee factor applied to all bundled units on site with a licensed thermal power rating less than or equal to 2,000 MWt. For the first bundled unit on a site with a licensed thermal power rating greater than 250 MWt and less than or equal to 2,000 MWt, the variable rate is based on the difference between the maximum fee and the minimum fee, divided by 1,750 MWt (the variable fee licensed thermal rating range). For additional bundled units with a licensed thermal power rating less than or equal to 2,000 MWt, the variable rate is based on the maximum fee divided by 2,000 MWt.

■ 3. In § 171.15, revise paragraph (e)(1) to read as follows:

§ 171.15 Annual fees: Reactor licenses and independent spent fuel storage licenses.

* * * * *

(e)(1) Each person holding an operating license for an SMR issued under 10 CFR part 50 or a combined license issued under 10 CFR part 52 after the Commission has made the finding under 10 CFR 52.103(g), shall pay the annual fee for all licenses held for an SMR site. The annual fee will be determined using the cumulative licensed thermal power rating of all SMR units and the bundled unit concept, during the fiscal year in which the fee is due. For a given site, the use of the bundled unit concept is independent of the number of SMR plants, the number of SMR licenses issued, or the sequencing of the SMR licenses that have been issued.

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Dated at Rockville, Maryland, this 8th day of July 2016.

For the Nuclear Regulatory Commission.

Theresa Barczy,

Acting Branch Chief, Rules, Announcements and Directives Branch, Division of Administrative Services, Office of Administration.

[FR Doc. 2016–16659 Filed 7–14–16; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 23

[Docket No. FAA–2016–3462; Notice No. 23–275–SC]

Special Conditions: Cirrus Design Corporation, Model SF50; Whole Airplane Parachute Recovery System

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final special conditions.

SUMMARY: These special conditions are issued for the Cirrus Design Corporation (Cirrus), model SF50 airplane. This airplane will have a novel or unusual design feature(s) associated with a whole airplane parachute recovery system. The applicable airworthiness regulations do not contain adequate or appropriate safety standards for this design feature. These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

DATES: These special conditions are effective August 15, 2016 and are applicable on July 6, 2016.

FOR FURTHER INFORMATION CONTACT: Mr. Bob Stegeman, Federal Aviation Administration, Aircraft Certification Service, Small Airplane Directorate, ACE–111, 901 Locust; Kansas City, Missouri 64106; telephone (816) 329–4140; facsimile (816) 329–4090.

SUPPLEMENTARY INFORMATION:

Background

On September 9, 2008, Cirrus Design Corporation applied for a type certificate for their new SF50 airplane. The SF50 is a seven seat (five adults and two children), pressurized, retractable gear, carbon composite, single engine jet airplane. The airplane will have a Maximum Take-Off Weight of 6,000 pounds, a Maximum Operating Speed of 250 Knots Calibrated Airspeed (KCAS), and a Maximum Operating Altitude of 28,000 feet.

Cirrus intends to install a whole airplane ballistic parachute system (BPS) called the Cirrus Airframe Parachute System (CAPS). This installation couples the BPS with the automatic flight controls. The CAPS will be installed as standard equipment on the SF50 airplane. Unlike the SR20 and SR22 airplanes CAPS, the SF50 CAPS is a supplemental system and no credit for the system will be used to meet part 23 requirements. The SF50 CAPS design will require some performance enhancements over existing technology used in other BPS.

The system will consist of the recovery parachute, activation and deployment systems, and autopilot functions. The SF50 CAPS will be designed for a higher gross weight, maximum activation speed, and maximum operating altitude.

Whole airplane parachute recovery systems are intended to save the lives of the occupants in life-threatening situations for which normal emergency procedures have been exhausted. Potential emergencies include, but are not limited to—loss of power or thrust; loss of airplane control; pilot disorientation; pilot incapacitation with a passenger on board; mechanical or structural failure; icing; and accidents resulting from pilot negligence or error. The recovery system should prioritize protection from most probable hazards, but it is not reasonable to expect it to protect occupants from every possible situation.

This technology, which was originally developed for ultralight and experimental aircraft, was first approved for general aviation airplanes with a Supplemental Type Certificate for the Cessna model 150/152 airplanes. The FAA issued special conditions for these airplanes to incorporate ballistic recovery systems on October 22, 1987 (Special Condition No. 23–ACE–33; Ballistic Recovery System, Inc., Modified Cessna 150/A150 Series Airplanes and 152/A152 Model Airplanes to Incorporate the GARD–150 System; Docket No. 037CE) (FR Doc. 87–26420, November 11, 1987). These special conditions were later modified for the other general aviation airplanes (Special Condition No. 23–ACE–76; Ballistic Recovery Systems, Modified for Small General Aviation Airplanes; Docket No. 118CE) (FR Doc. 94–16233, August 5, 1994), including the Cirrus Design Corporation SR20 airplanes (Special Condition No. 23–ACE–88, Ballistic Recovery Systems Cirrus SR20 Installation, Docket No. 136CE) (FR Doc. 97–27504, October 15, 1997).

The previously FAA-approved BPS consists of a parachute packed in a compartment within the airframe. A solid propellant rocket motor, adjacent to the parachute pack, extracts the parachute. A mechanical pull handle mounted within reach of the pilot and copilot or passenger activates the system. At least two separate independent actions are necessary to activate the system.

In addition to a normal BPS, the SF50 CAPS system will incorporate an airbag to assist deployment and a system for sequencing deployment and interfacing with the airplane's avionics. The avionics interface is intended to bring the airplane within a valid deployment envelope speed (67–160 KCAS).

The SF50 CAPS is a non-required system that differs from other BPS in that it will interact with the flight control system and other airplane systems. The baseline special conditions must incorporate the required level of safety for the normal BPS as well as the aspect that interfaces with the airplane. Since it is a non required system, additional latitude exists to evaluate and substantiate the system so it will present no additional hazards.

Type Certification Basis

Under the provisions of 14 CFR 21.17, Cirrus Design Corporation must show that the SF50 meets the applicable provisions of part 23, as amended by amendments 23–1 through 23–62 thereto.

If the Administrator finds that the applicable airworthiness regulations (*i.e.,* 14 CFR part 23) do not contain adequate or appropriate safety standards for the SF50 because of a novel or unusual design feature, special conditions are prescribed under the provisions of § 21.16.

In addition to the applicable airworthiness regulations and special conditions, the SF50 must comply with the fuel vent and exhaust emission requirements of 14 CFR part 34 and the noise certification requirements of 14 CFR part 36 and the FAA must issue a finding of regulatory adequacy under section 611 of Public Law 92–574, the "Noise Control Act of 1972."

The FAA issues special conditions, as defined in 14 CFR 11.19, in accordance with § 11.38, and they become part of the type-certification basis under § 21.17(a)(2).

Special conditions are initially applicable to the model for which they are issued. Should the type certificate for that model be amended later to include any other model that incorporates the same or similar novel or unusual design feature, the special conditions would also apply to the other model under § 21.101.

Novel or Unusual Design Features

The SF50 will incorporate the following novel or unusual design features: A whole-airplane parachute recovery system that is a supplemental safety system and unlike any previously approved BPS, will add enhancements that assist deployment and autopilot functions that work to bring the airplane into an acceptable deployment envelope.

Discussion

This system is a non-required system that will interact with the flight control system. These special conditions must incorporate the required level of safety for the normal ballistic parachute system as established by Special Condition 23–ACE–76 in addition to the aspect that interfaces with the airplane.

The FAA revised § 23.1309, Equipment, systems, and installations, in amendment 23–62 (76 FR 75736, December 2, 2011) to address two different types of equipment and systems installed in the airplane. This system operates at the limit of the normal operating envelope and challenges normal expectations of such a supplemental system. Amendment 23–62 preamble states: Section 23.1309 lists the qualifiers "under the airplane operating and environmental conditions".

Section 23.1309, amendment 23–62 preamble also describes two actions for the applicant. First, the applicant must consider the full normal operating envelope of the airplane, as defined by the Airplane Flight Manual, with any modification to that envelope associated with abnormal or emergency procedures and any anticipated flightcrew action. Second, the applicant must consider the anticipated external and internal airplane environmental conditions, as well as any additional conditions where equipment and systems are assumed to "perform as intended".

Section 23.1309(a)(2) requires analysis of any installed equipment or system with potential failure conditions that are catastrophic, hazardous, major, or minor, to determine their impact on the safe operation of the airplane. The applicant must show that they do not adversely affect proper functioning of the equipment, systems, or installations covered by § 23.1309 and do not otherwise adversely influence the safety of the airplane or its occupants.

Section 23.1309(a)(2) does not mandate that non-required equipment and systems function properly during all airplane operations once in service, provided all potential failure conditions have no effect on the safe operation of the airplane. The equipment or system must function in the manner expected by the manufacturer's operating manual for the equipment or system. An applicant's statement of intended function must be sufficiently detailed so the FAA can evaluate whether the system is appropriate for its intended function(s).

To incorporate the intent of amendment 23–62, the FAA issues these special conditions to include previous BPS special conditions, address the interaction CAPS with other airplane systems, and that it is a non-required system. The system must function within specified manufacturer's limits while operated within the manufacturers recommended envelope. Since it is a non-required system, the means of substantiation have been altered to reflect the bounds of the operating envelope, the means of analysis that can be substantiated with overlapping lower-level testing/analysis, and relieve in-flight deployment to avoid unnecessary expense and the inherent danger in performing this test.

All special condition requirements must meet two fundamental criteria:

- The installed system must not introduce unacceptable hazards prior to or after activation.
- The applicant must show that the system does not adversely affect proper functioning of the equipment, systems, or installations covered by § 23.1309 and do not otherwise adversely influence the safety of the airplane or its occupants.

The applicant does not have to demonstrate the system in flight on a test airplane.

Discussion of Comments

Notice of proposed special conditions No. 23–16–01–SC for the Cirrus Design Corporation SF50 airplanes was published in the **Federal Register** on March 18, 2016 (81 FR 14801). The FAA received 11 comments that disagreed with the special condition provisions for demonstration via test or test supported by analysis. These comments primarily focused on the concern that the FAA should require testing of the BPS in flight to validate intended performance.

The process of an applicant showing compliance to these BPS system special conditions is a complex and multi-tiered process. The applicant must conservatively demonstrate each function of the entire deployment event sequentially, from pulling the handle to securing the airplane after ground impact, to meet the special conditions. These separate events and functions can be demonstrated to satisfy the requirements of these special conditions with lower-level testing, normally using analysis supported by test. This is consistent with certification methods used on many other parts of the airplane.

The FAA decision to allow a means of compliance without requiring inflight deployment on a test airplane is not a complete elimination of testing or an evaluation of the system. The FAA believes that test or analysis supported by test will provide an acceptable level of safety to demonstrate that the system will perform its intended function; therefore, no in-flight deployment on a test airplane will be required.

The Cirrus SF50 BPS is a non-required safety device intended to improve occupant survivability in emergencies and under extreme conditions. The certification requirements contained in these special conditions are consistent with the requirements of §§ 23.1301(a) and 23.1309(a) for equipment that is not required for type certification or by the operating rules. Because the BPS is non-required equipment, its design must be shown to be appropriate for the intended function and it must not adversely affect safety. The FAA Aircraft Certification Service has evaluated the intended function, design, and installation of the SF50 BPS, and has considered what is required to meet an acceptable confidence level.

The potential operational decision to deploy the BPS in service would be the result of an emergency, one that will invariably result in a controlled crash. While the BPS is expected to improve occupant survivability in an emergency, the residual risk to the occupants is not completely eliminated. The primary hazard introduced while performing a comprehensive BPS flight test is the risk to the flight test crew when exposed to controlled crash conditions during a successful deployment. The FAA has determined the requirement to demonstrate the BPS via testing or testing supported by analysis to be "appropriate for the intended function and does not adversely affect safety". Therefore, the FAA will not require a comprehensive flight test deployment.

Another commenter requested clarification of paragraph 1(c)(3), regarding definition of occupant protection after aircraft structure damage. To clarify, the FAA's intent of this paragraph was to ensure that the cabin can protect the occupants after a normal deployment even if the cabin experiences damage resulting from the deployment process or as a result of ground impact. The paragraph does not assume any airplane damage prior to system deployment.

Applicability

As discussed above, these special conditions are applicable to the SF50. Should Cirrus apply at a later date for a change to the type certificate to include another model incorporating the same novel or unusual design feature, the special conditions would apply to that model as well.

Under standard practice, the effective date of final special conditions would be 30 days after the date of publication in the **Federal Register**; however, as the certification date for the Cirrus SF50 is imminent, the FAA finds that good cause exists to make these special conditions effective upon issuance.

Conclusion

This action affects only certain novel or unusual design features on one model of airplane. It is not a rule of general applicability and it affects only the applicant who applied to the FAA for approval of these features on the airplane.

List of Subjects in 14 CFR Part 23

Aircraft, Aviation safety, Signs and symbols.

Citation

The authority citation for these special conditions is as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701, 14 CFR 11.38, 11.39, 21.16 and 21.17.

The Special Conditions

Accordingly, pursuant to the authority delegated to me by the Administrator, the following special conditions are issued as part of the type certification basis for Cirrus SF50 airplanes.

1. Whole Airplane Parachute Recovery System With Flight Control and Deployment Augmentation.

(a) System Validation.

(1) The applicant must demonstrate by test, or analysis supported by test, that the system will not cause an unacceptable hazard or otherwise exceed the system deployment design loads for the critical flight conditions.

(2) The recovery system activation envelope must include speeds at or near V_S up to at least V_o. The applicant must satisfactorily demonstrate by test, or by analysis supported by test, the logic and automatic control interface that allow the recovery system activation over this speed range.

(b) Occupant Restraint.

Each seat in the airplane must be equipped with an approved restraint system, which will protect the occupants from serious head and upper torso injuries during a recovery system deployment and ground impact at the critical load conditions.

(c) Parachute Performance.

(1) A 1.5 factor of safety applied to the limit load must be used for all components of the recovery system as well as the attachment structure, the cabin structure surrounding the occupants, and any interconnecting structure of the airplane. Limit loads are defined as the parachute deployment forces developed within the operational envelope of the system. Lower factors of safety for airplane weight and velocity may be used, so that when combined in the energy equation, represent a 1.5 factor of safety of the energy equation.

(2) Stitching must be of a type that will not ravel when broken.

(3) The applicant must show via test, or analysis supported by test, that with the recovery parachute deployed and the airplane structure damaged, the airplane impact during touchdown will result in an occupant environment in which serious injury to the occupants is improbable.

(4) The applicant must show via test, or analysis supported by test, that with the recovery parachute deployed, the airplane can impact the ground in various adverse weather conditions, including winds up to 15 knots, without endangering the airplane occupants at and after touchdown.

(d) System Function and Operations.

(1) The installation design and location of the extraction device must consider fire hazards associated with the activation of the parachute system and reduce this potential as much as possible without compromising function of the extraction device.

(2) A system safety analysis will be conducted on the recovery system that will consider the effects of annunciated and un-annunciated failures. This analysis will address both losses of function as well as malfunction (including un-commanded system activation). The applicant must show that they do not adversely affect proper functioning of the equipment, systems, or installations covered by § 23.1309, and do not otherwise adversely influence the safety of the airplane or its occupants. It must be shown that reliable and functional deployment in the adverse weather conditions that the airplane is approved for have been considered. For example, if the airplane is certified for flight in icing conditions, and flight test in icing reveals that ice may cover the deployment area, then the possible adverse effects of ice or an ice layer covering the parachute deployment area should be analyzed.

(3) The recovery system must be designed to safeguard against inadvertent activation. Two separate and intentional actions will be required to activate the system.

(4) It must be demonstrated that the system can be activated without difficulty by occupants of various sizes, from a 10th percentile female to a 90th percentile male, while sitting in the pilot or copilot seat.

(5) The system must be labeled for identification, function, and operating limitations.

(6) The airplane must be equipped with ASTM F 2316–06 conforming placards suitable to draw attention of first responders. Section 11 of ASTM F 2316–06, specifies that the airplane should be marked with a "danger" placard placed adjacent to the exit point of each rocket/parachute, an "identifying" placard attached to each rocket, and "warning" placard(s) applied where occupant(s) enter the airplane or where rescue personnel can readily see the placard(s).

(e) Design and Construction.

(1) All components of the system must be protected against deterioration due to weathering, corrosion, and abrasion.

(2) Adequate provisions must be made for ventilation and drainage of the system compartments and associated structure to ensure the sound condition of the system.

(f) Materials and workmanship.

(1) The suitability and durability of materials used for parts, the failure of which could adversely affect safety, must—

i. Be established by experience or tests;

ii. Meet approved specifications that ensure their having the strength and other properties assumed in the design data; and

iii. Take into account the effects of environmental conditions, such as temperature and humidity, expected in service.

(2) Workmanship must be of a high standard.

(3) The parachute(s) must be identified with a data panel that defines the Manufacturer, Date of Manufacture, Part Number, and Serial Number.

(g) Systems Maintenance and Inspection.

(1) Instructions for continued airworthiness must be prepared for the system that meet the requirements of § 23.1529.

(2) Adequate means must be provided to permit the close examination of the system components to ensure proper functioning, alignment, lubrication, and adjustment during the required inspection of the system.

(h) Operating Limitations.

(1) Operating limitations must be prescribed to ensure proper operation of the system. A detailed discussion of the system, including operation, limitations, and deployment envelope must be included in the Airplane Flight Manual.

(2) Operating limitations must be prescribed for inspecting and overhauling the system components at approved intervals.

Issued in Kansas City, Missouri, on July 6, 2016.

William Schinstock,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2016–16813 Filed 7–14–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 25

[Docket No. FAA–2016–4237; Special Conditions No. 25–619–SC]

Special Conditions: Gulfstream Aerospace Corporation Model GVII–G500 Airplanes; Isolation or Protection of Airplane Electrical-System Security From Unauthorized Internal Access

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final special conditions; request for comments.

SUMMARY: These special conditions are issued for the Gulfstream Aerospace Corporation (Gulfstream) Model GVII–G500 airplane. This airplane will have a novel or unusual design feature when compared to the state of technology envisioned in the airworthiness standards for transport-category airplanes. This design feature is a digital systems architecture requiring isolation or protection from unauthorized internal access. The applicable airworthiness regulations do not contain adequate or appropriate safety standards for this design feature. These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

DATES: This action is effective on Gulfstream on July 15, 2016. We must receive your comments by August 29, 2016.

ADDRESSES: Send comments identified by docket number FAA–2016–4237 using any of the following methods:

- *Federal eRegulations Portal:* Go to *http://www.regulations.gov/* and follow the online instructions for sending your comments electronically.
- *Mail:* Send comments to Docket Operations, M–30, U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE., Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* Fax comments to Docket Operations at 202–493–2251.

Privacy: The FAA will post all comments it receives, without change, to *http://www.regulations.gov/*, including any personal information the commenter provides. Using the search function of the docket Web site, anyone can find and read the electronic form of all comments received into any FAA docket, including the name of the individual sending the comment (or signing the comment for an association, business, labor union, etc.). DOT's complete Privacy Act Statement can be found in the **Federal Register** published on April 11, 2000 (65 FR 19477–19478), as well as at *http://DocketsInfo.dot.gov/*.

Docket: Background documents or comments received may be read at *http://www.regulations.gov/* at any time. Follow the online instructions for accessing the docket or go to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Varun Khanna, FAA, Airplane and Flightcrew Interface Branch, ANM–111, Transport Airplane Directorate, Aircraft Certification Service, 1601 Lind Avenue SW., Renton, Washington 98057–3356; telephone 425–227–1298; facsimile 425–227–1320.

SUPPLEMENTARY INFORMATION: The FAA has determined that notice of, and opportunity for prior public comment on, these special conditions is unnecessary because the substance of these special conditions has been subject to the public comment process in several prior instances with no substantive comments received. The FAA therefore finds that good cause exists for making these special conditions effective upon publication in the **Federal Register**.

Comments Invited

We invite interested people to take part in this rulemaking by sending written comments, data, or views. The most helpful comments reference a specific portion of the special conditions, explain the reason for any recommended change, and include supporting data.

We will consider all comments we receive by the closing date for comments. We may change these special conditions based on the comments we receive.

Background

On March 29, 2012, Gulfstream Aerospace Corporation applied for a type certificate for their new Model GVII–G500 airplane. The Model GVII–G500 airplane will be a business jet capable of accommodating up to 19 passengers. It will incorporate a low, swept-wing design with winglets and a T-tail. The powerplant will consist of two aft-fuselage-mounted Pratt & Whitney turbofan engines.

Type Certification Basis

Under Title 14, Code of Federal Regulations (14 CFR) 21.17, Gulfstream must show that the Model GVII–G500 airplane meets the applicable provisions of 14 CFR part 25, as amended by Amendments 25–1 through 25–129.

If the Administrator finds that the applicable airworthiness regulations (*i.e.*, part 25) do not contain adequate or appropriate safety standards for the Model GVII–G500 airplane because of a novel or unusual design feature, special conditions are prescribed under the provisions of § 21.16.

Special conditions are initially applicable to the model for which they are issued. Should the type certificate for that model be amended later to include any other model that incorporates the same or similar novel or unusual design feature, the special conditions would also apply to the other model under § 21.101.

In addition to the applicable airworthiness regulations and special conditions, Model GVII–G500 airplanes must comply with the fuel-vent and exhaust-emission requirements of 14 CFR part 34, and the noise-certification requirements of 14 CFR part 36. The FAA must issue a finding of regulatory adequacy under § 611 of Public Law 92–574, the "Noise Control Act of 1972."

The FAA issues special conditions, as defined in 14 CFR 11.19, in accordance with § 11.38, and they become part of the type certification basis under § 21.17(a)(2).

Novel or Unusual Design Features

The Model GVII–G500 airplane will incorporate the following novel or unusual design feature: A digital systems architecture requiring isolation or protection from unauthorized internal access.

Discussion

Networks, both in safety-related and non-safety-related applications, have been implemented in existing commercial-production airplanes. However, network security considerations and functions have played a relatively minor role in the certification of such systems because of the isolation, protection mechanisms, and limited connectivity between these networks.

To provide an understanding of the airplane electronic equipment, systems, and assets, these special conditions use the concept of domains. However, this does not prescribe any particular architecture.

The aircraft-control domain consists of the airplane electronic systems, equipment, instruments, networks, servers, software and hardware components, databases, etc., which are part of the type design of the airplane and are installed in the airplane to enable the safe operation of the airplane. These can also be referred to as flight-safety-related systems, and include flight controls, communication, display, monitoring, navigation, and related systems.

The airline-information-services domain generally consists of functions that the airplane operator manages or controls, such as administrative functions, cabin-support functions, etc.

The passenger-information-services domain consists of all functions required to provide the passengers with information.

The Gulfstream Model GVII–G500 airplane design introduces the potential for access to aircraft-control domain and airline-information-services domain by unauthorized persons through the passenger-information-services domain; and the security vulnerabilities related to the introduction of viruses, worms, user mistakes, and intentional sabotage of airplane networks, systems, and databases.

For electronic systems-and-assets security in these domains, the level of protection provided against security threats should be based on a security-risk assessment, noting that the level of protection could differ between domains and within domains, depending on the security threat. For each security vulnerability and airplane electronic asset, Gulfstream should identify in which domain the asset will be addressed.

In addition, the operating systems for current airplane systems are usually and historically proprietary. Therefore, they are not as susceptible to corruption from worms, viruses, and other malicious actions as are more-widely used commercial operating systems, such as Microsoft Windows NT, because access to the design details of these proprietary operating systems is limited to the system developer and airplane integrator. Some systems installed on the Gulfstream Model GVII–500 will use operating systems that are widely used and commercially available from third-party software suppliers. The security vulnerabilities of these operating systems may be more widely known than are the vulnerabilities of proprietary operating systems that the avionics manufacturers currently use.

Applicability

As discussed above, these special conditions are applicable to the Gulfstream Model GVII–G500 airplane. Should Gulfstream apply at a later date for a change to the type certificate to include another model incorporating the same novel or unusual design feature, these special conditions would apply to that model as well.

Conclusion

This action affects only a certain novel or unusual design feature on one model series of airplanes. It is not a rule of general applicability.

The substance of these special conditions has been subjected to the notice and comment period in several prior instances and has been derived without substantive change from those previously issued. It is unlikely that prior public comment would result in a significant change from the substance contained herein. Therefore, the FAA has determined that prior public notice and comment are unnecessary, and good cause exists for adopting these special conditions upon publication in the **Federal Register**.

The FAA is requesting comments to allow interested persons to submit views that may not have been submitted in response to the prior opportunities for comment described above.

List of Subjects in 14 CFR Part 25

Aircraft, Aviation safety, Reporting and recordkeeping requirements.

The authority citation for these special conditions is as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701, 44702, 44704.

The Special Conditions

Accordingly, pursuant to the authority delegated to me by the Administrator, the following special conditions are issued as part of the type certification basis for Gulfstream Model GVII–G500 airplane.

Isolation or Security Protection of the Aircraft Control Domain and the Airline Information Services Domain From the Passenger Services Domain

1. Gulfstream must ensure that the Model GVII–G500 series airplane design provides isolation from, or airplane electronic-system security protection against, access by unauthorized sources internal to the airplane. The design must prevent inadvertent and malicious changes to, and all adverse impacts upon, airplane equipment, systems, networks, or other assets required for safe flight and operations.

2. Gulfstream must establish appropriate procedures to allow the operator to ensure that continued airworthiness of the Model GVII–G500 series airplane is maintained, including all post-type-certification modifications that may have an impact on the approved electronic-system security safeguards.

Issued in Renton, Washington, on July 7, 2016.

Michael Kaszycki,

Assistant Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2016–16638 Filed 7–14–16; 8:45 am]

BILLING CODE 4910–13–P

PENSION BENEFIT GUARANTY CORPORATION

29 CFR Part 4022

Benefits Payable in Terminated Single-Employer Plans; Interest Assumptions for Paying Benefits

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Final rule.

SUMMARY: This final rule amends the Pension Benefit Guaranty Corporation's regulation on Benefits Payable in Terminated Single-Employer Plans to prescribe interest assumptions under the regulation for valuation dates in August 2016. The interest assumptions are used for paying benefits under terminating single-employer plans covered by the pension insurance system administered by PBGC.

DATES: Effective August 1, 2016.

FOR FURTHER INFORMATION CONTACT: Deborah C. Murphy (*Murphy.Deborah@pbgc.gov*), Assistant General Counsel for Regulatory Affairs, Pension Benefit Guaranty Corporation, 1200 K Street NW., Washington, DC 20005, 202–326–4400 ext. 3451. (TTY/TDD users may call the Federal relay service toll-free at

1–800–877–8339 and ask to be connected to 202–326–4400 ext. 3451).

SUPPLEMENTARY INFORMATION: PBGC's regulation on Benefits Payable in Terminated Single-Employer Plans (29 CFR part 4022) prescribes actuarial assumptions—including interest assumptions—for paying plan benefits under terminating single-employer plans covered by title IV of the Employee Retirement Income Security Act of 1974. The interest assumptions in the regulation are also published on PBGC's Web site (*http://www.pbgc.gov*).

PBGC uses the interest assumptions in Appendix B to Part 4022 to determine whether a benefit is payable as a lump sum and to determine the amount to pay. Appendix C to Part 4022 contains interest assumptions for private-sector pension practitioners to refer to if they wish to use lump-sum interest rates determined using PBGC's historical methodology. Currently, the rates in Appendices B and C of the benefit payment regulation are the same.

The interest assumptions are intended to reflect current conditions in the financial and annuity markets. Assumptions under the benefit payments regulation are updated monthly. This final rule updates the benefit payments interest assumptions for August 2016.[1]

The August 2016 interest assumptions under the benefit payments regulation will be 0.50 percent for the period during which a benefit is in pay status and 4.00 percent during any years preceding the benefit's placement in pay status. In comparison with the interest assumptions in effect for July 2016, these interest assumptions represent a decrease of 0.25 percent in the immediate annuity rate and are otherwise unchanged.

PBGC has determined that notice and public comment on this amendment are impracticable and contrary to the public interest. This finding is based on the need to determine and issue new interest assumptions promptly so that the assumptions can reflect current market conditions as accurately as possible.

Because of the need to provide immediate guidance for the payment of benefits under plans with valuation dates during August 2016, PBGC finds that good cause exists for making the assumptions set forth in this amendment effective less than 30 days after publication.

PBGC has determined that this action is not a "significant regulatory action" under the criteria set forth in Executive Order 12866.

Because no general notice of proposed rulemaking is required for this amendment, the Regulatory Flexibility Act of 1980 does not apply. See 5 U.S.C. 601(2).

List of Subjects in 29 CFR Part 4022

Employee benefit plans, Pension insurance, Pensions, Reporting and recordkeeping requirements.

In consideration of the foregoing, 29 CFR part 4022 is amended as follows:

PART 4022—BENEFITS PAYABLE IN TERMINATED SINGLE–EMPLOYER PLANS

■ 1. The authority citation for part 4022 continues to read as follows:

Authority: 29 U.S.C. 1302, 1322, 1322b, 1341(c)(3)(D), and 1344.

■ 2. In appendix B to part 4022, Rate Set 274, as set forth below, is added to the table.

Appendix B to Part 4022—Lump Sum Interest Rates for PBGC Payments

* * * * *

Rate set	For plans with a valuation date		Immediate annuity rate (percent)	Deferred annuities (percent)				
	On or after	Before		i_1	i_2	i_3	n_1	n_2
*		*	*	*	*		*	*
274	8–1–16	9–1–16	0.50	4.00	4.00	4.00	7	8

■ 3. In appendix C to part 4022, Rate Set 274, as set forth below, is added to the table.

Appendix C to Part 4022—Lump Sum Interest Rates for Private-Sector Payments

* * * * *

Rate set	For plans with a valuation date		Immediate annuity rate (percent)	Deferred annuities (percent)				
	On or after	Before		i_1	i_2	i_3	n_1	n_2
*		*	*	*	*		*	*
274	8–1–16	9–1–16	0.50	4.00	4.00	4.00	7	8

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[1] Appendix B to PBGC's regulation on Allocation of Assets in Single-Employer Plans (29 CFR part 4044) prescribes interest assumptions for valuing benefits under terminating covered single-employer plans for purposes of allocation of assets under ERISA section 4044. Those assumptions are updated quarterly.

Issued in Washington, DC, on this 11th day of July 2016.

Judith Starr,

General Counsel, Pension Benefit Guaranty Corporation.

[FR Doc. 2016–16728 Filed 7–14–16; 8:45 am]

BILLING CODE 7709–02–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2016–0635]

Drawbridge Operation Regulation; Lake Washington Ship Canal, Seattle, WA

AGENCY: Coast Guard, DHS.

ACTION: Notice of temporary deviation from drawbridge regulation.

SUMMARY: The Coast Guard has issued a temporary deviation from the operating schedule that governs Seattle Department of Transportation's (SDOT) Fremont Bridge, across the Lake Washington Ship Canal, mile 2.6, at Seattle, WA. The deviation is necessary to accommodate heavy pedestrian and cycling traffic across the bridge during the 'Fun Ride' fundraising event. The deviation allows the bridge to remain in the closed-to-navigation position and need not open to maritime traffic.

DATES: This deviation is effective from 10:30 a.m. to 12:30 p.m. on August 14, 2016.

ADDRESSES: The docket for this deviation, [USCG–2016–0635] is available at *http://www.regulations.gov.* Type the docket number in the "SEARCH" box and click "SEARCH." Click on Open Docket Folder on the line associated with this deviation.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary deviation, call or email Mr. Steven Fischer, Bridge Administrator, Thirteenth Coast Guard District; telephone 206–220–7282, email *d13-pf-d13bridges@uscg.mil.*

SUPPLEMENTARY INFORMATION: Seattle Department of Transportation (SDOT) has requested a temporary deviation from the operating schedule for the Fremont Bridge, mile 2.6, crossing the Lake Washington Ship Canal at Seattle, WA. The deviation is necessary to accommodate heavy pedestrian and cycling traffic across the bridge during the 'Fun Ride' fundraising event. To facilitate this event, the double bascule draw of the bridge will not open for vessel traffic during said date and time. The Fremont Bridge provides a vertical clearance of 14 feet (31 feet of vertical clearance for the center 36 horizontal feet) in the close-to-navigation position. The clearance is referenced to the mean water elevation of Lake Washington. The normal operating schedule for the Fremont Bridge is 33 CFR 117.1051. Waterway usage on the Lake Washington Ship Canal ranges from commercial tug and barge to small pleasure craft.

Vessels able to pass through the bridge in the closed-to-navigation position may do so at anytime. The bridge will be able to open for emergencies, and there is no immediate alternate route for vessels to pass. The Coast Guard will also inform the users of the waterways through our Local and Broadcast Notices to Mariners of the change in operating schedule for the bridge so that vessels can arrange their transits to minimize any impact caused by the temporary deviation.

In accordance with 33 CFR 117.35(e), the drawbridge must return to its regular operating schedule immediately at the end of the designated time period. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: July 11, 2016.

Steven M. Fischer,

Bridge Administrator, Thirteenth Coast Guard District.

[FR Doc. 2016–16736 Filed 7–14–16; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2016–0632]

Drawbridge Operation Regulation; Mianus River, Greenwich, CT

AGENCY: Coast Guard, DHS.

ACTION: Notice of deviation from drawbridge regulation.

SUMMARY: The Coast Guard has issued a temporary deviation from the operating schedule that governs the Metro-North Bridge across the Mianus River, mile 1.0, at Greenwich, Connecticut. This deviation is necessary to allow the bridge owner to perform superstructure repairs and replace timber ties.

DATES: This deviation is effective from 8 a.m. on September 12, 2016 to 8 a.m. on September 26, 2016.

ADDRESSES: The docket for this deviation, [USCG–2016–0632] is available at *http://www.regulations.gov.* Type the docket number in the "SEARCH" box and click "SEARCH". Click on Open Docket Folder on the line associated with this deviation.

FOR FURTHER INFORMATION CONTACT: If you have questions about this temporary deviation, call or email Judy Leung-Yee, Project Officer, First Coast Guard District, telephone (212) 514–4330, email *judy.k.leung-yee@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Metro-North Bridge, mile 1.0, across the Mianus River, has a vertical clearance in the closed position of 20 feet at mean high water and 27 feet at mean low water. The existing bridge operating regulations are found at 33 CFR 117.209.

The waterway is transited by seasonal recreational traffic.

Connecticut DOT, the owner of the bridge, requested a temporary deviation from the normal operating schedule to perform steel repairs and replace timber ties.

Under this temporary deviation, the Metro-North Bridge will operate according to the schedule below:

a. From September 12, 2016 8 a.m. to September 16, 2016 4 a.m. the bridge will not open to marine traffic.

b. From September 16, 2016 4 a.m. to September 19, 2016 8 a.m. the bridge will open fully on signal upon 24 hour advance notice.

c. From September 19, 2016 8 a.m. to September 23, 2016 4 a.m. the bridge will not open to marine traffic.

d. From September 23, 2016 4 a.m. to September 26, 2016 8 a.m. the bridge will open fully on signal upon 24 hour advance notice.

Vessels able to pass under the bridge in the closed position may do so at any time. The bridge will not be able to open for emergencies and there is no immediate alternate route for vessels to pass.

The Coast Guard will inform the users of the waterways through our Local Notice and Broadcast to Mariners of the change in operating schedule for the bridge so that vessel operations can arrange their transits to minimize any impact caused by the temporary deviation.

In accordance with 33 CFR 117.35(e), the drawbridge must return to its regular operating schedule immediately at the end of the effective period of this temporary deviation. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: July 12, 2016.

C.J. Bisignano,

Supervisory Bridge Management Specialist, First Coast Guard District.

[FR Doc. 2016–16775 Filed 7–14–16; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2016–0624]

RIN 1625–AA00

Safety Zone; Lake Erie Open Water Classic; Lake Erie, Cleveland, OH

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone on Lake Erie, Cleveland, OH. This safety zone is intended to restrict vessels from a portion of Lake Erie during the Lake Erie Open Water Classic open water swim on July 16, 2016. This temporary safety zone is necessary to protect swimmers from vessels operating in the area. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port Buffalo.

DATES: This rule is effective from 5:45 a.m. until 11:15 a.m. on July 16, 2016.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* type USCG–2016–0624 in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions about this proposed rulemaking, call or email LT Stephanie Pitts, Chief of Waterways Management, U.S. Coast Guard Marine Safety Unit Cleveland; telephone 216–937–0128, email *Stephanie.M.Pitts@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR	Code of Federal Regulations
DHS	Department of Homeland Security
FR	Federal Register
NPRM	Notice of proposed rulemaking
Pub. L.	Public Law
§	Section
U.S.C.	United States Code

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because doing so would be impracticable and contrary to the public interest. The final details for this event were not known to the Coast Guard until there was insufficient time remaining before the event to publish an NPRM. Thus, delaying the effective date of this rule to wait for a comment period to run would be both impracticable and contrary to the public interest because it would inhibit the Coast Guard's ability to protect spectators and vessels from the hazards associated with the presence of swimmers in open water.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this temporary rule effective less than 30 days after publication in the **Federal Register**. For the same reasons discussed in the preceding paragraph, waiting for a 30 day notice period to run would be contrary to the public interest given the need to ensure the safety and security of the event and participants.

III. Legal Authority and Need for Rule

The Coast Guard issues this rule under authority in 33 U.S.C. 1231. On July 16, 2016, between 5:45 a.m. and 11:15 a.m., a large scale swimming event will take place on Lake Erie in Cleveland, OH. The Captain of the Port Buffalo (COTP) has determined that a large scale swimming event on a navigable waterway will pose a significant risk to participants and the boating public. This rule is needed to protect personnel, vessels, and the marine environment in the navigable waters within the safety zone while the Open Water Classic is happening.

IV. Discussion of the Rule

This rule establishes a safety zone from 5:45 a.m. to 11:15 a.m. on July 16, 2016. The safety zone will encompass all waters of Lake Erie, Cleveland, OH south of a line drawn between position 41°29′31″ N., 081°44′23″ W. and 41°29′24″ N., 081°45′05″ W. (NAD 83) to the shore. No vessel or person will be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative. The Captain of the Port or his designated representative may be contacted via VHF Channel 16.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and executive orders (E.O.s) related to rulemaking. Below we summarize our analyses based on a number of these statutes and E.O.s, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, as supplemented by Executive Order 13563, Improving Regulation and Regulatory Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of Executive Order 12866 or under section 1 of Executive Order 13563. The Office of Management and Budget has not reviewed it under those Orders.

We conclude that this rule is not a significant regulatory action because we anticipate that it will have minimal impact on the economy, will not interfere with other agencies, will not adversely alter the budget of any grant or loan recipients, and will not raise any novel legal or policy issues. The safety zone created by this rule will be relatively small and enforced for a relatively short time. Also, the safety zone is designed to minimize its impact on navigable waters. Under certain conditions, vessels may still transit through the safety zone when permitted by the Captain of the Port.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the safety zone may be small entities, for the reasons stated in section V.A above, this rule will not have a significant economic impact on any vessel owner or operator.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under E.O. 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in E.O. 13132.

Also, this rule does not have tribal implications under E.O. 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. If you believe this rule has implications for federalism or Indian tribes, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section above.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a safety zone lasting less than 6 hours that will prohibit entry within a small area on Lake Erie. It is categorically excluded from further review under paragraph 34(g) of Figure 2–1 of the Commandant Instruction. An environmental analysis checklist supporting this determination and a Categorical Exclusion Determination are available in the docket where indicated under **ADDRESSES**. We seek any comments or information that may lead to the discovery of a significant environmental impact from this rule.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T09–0624 to read as follows:

§ 165.T09–0624 Safety Zone; Lake Erie Open Water Classic; Lake Erie, Cleveland, OH.

(a) The safety zone will encompass all waters of Lake Erie, Cleveland, OH south of a line drawn between position 41°29′31″ N., 081°44′23″ W. and 41°29′24″ N., 081°45′05″ W. (NAD 83) to the shore.

(b) *Enforcement period.* This regulation will be enforced on July 16, 2016 from 5:45 a.m. until 11:15 a.m.

(c) *Regulations.* (1) In accordance with the general regulations in § 165.23 of this part, entry into, transiting, or anchoring within this safety zone is prohibited unless authorized by the Captain of the Port Buffalo or his designated on-scene representative.

(2) This safety zone is closed to all vessel traffic, except as may be permitted by the Captain of the Port Buffalo or his designated on-scene representative.

(3) The "on-scene representative" of the Captain of the Port Buffalo is any Coast Guard commissioned, warrant or petty officer who has been designated by the Captain of the Port Buffalo to act on his behalf.

(4) Vessel operators desiring to enter or operate within the safety zone must contact the Captain of the Port Buffalo or his on-scene representative to obtain permission to do so. The Captain of the Port Buffalo or his on-scene representative may be contacted via VHF Channel 16. Vessel operators given permission to enter or operate in the safety zone must comply with all directions given to them by the Captain of the Port Buffalo, or his on-scene representative.

Dated: July 11, 2016.

B.W. Roche,

Captain, U.S. Coast Guard, Captain of the Port Buffalo.

[FR Doc. 2016–16799 Filed 7–14–16; 8:45 am]

BILLING CODE 9110–04–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 54

[WC Docket Nos. 11–42, 09–197, 10–90; FCC 16–38]

Lifeline and Link Up Reform and Modernization, Telecommunications Carriers Eligible for Universal Service Support, Connect America Fund

AGENCY: Federal Communications Commission.

ACTION: Final rule; correction.

SUMMARY: The Federal Communications Commission (FCC) published a

summary of the Commission's Third Report and Order, 81 FR 33026, May 24, 2016 which fully modernizes the Lifeline program so it supports broadband services and obtains high value from the expenditure of Universal Service funds. This document clarifies the effective dates for the rules as they were published in the **Federal Register**, in order to promote consistency with the effective dates found in the Commission's Third Report and Order. Additionally, this document clarifies rules subject to certain effective dates in order to reflect implementation changes being made to the program.

DATES: Effective July 15, 2016, except for the corrections to §§ 54.202, 54.405, 54.408, and 54.410, which contain information collection requirements that are not effective until approved by the Office of Management and Budget. The Federal Communications Commission will publish a separate document announcing such approval and the relevant effective date(s).

FOR FURTHER INFORMATION CONTACT: Christian Hoefly, Wireline Competition Bureau, Telecommunications Access Policy Division at (202) 418–3607 or at *christian.hoefly@fcc.gov.*

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 24, 2016, in FR Doc. 2016–11284, on page 33088, the following corrections are made:

Ordering Clauses [Corrected]

1. In the first column, paragraph 432 is corrected to read, "*It is further ordered,* that pursuant to the authority contained in Sections 1 through 4, 201 through 205, 254, 303(r), and 403 of the Communications Act of 1934, as amended, 47 U.S.C. 151 through 154, 201 through 205, 254, 303(r), and 403, and Section 706 of the Telecommunications Act of 1996, 47 U.S.C. 1302, part 54 of the Commission's rules, 47 CFR part 54, is amended, and such rule amendments to Sections 54.201 and 54.423 shall be effective 30 days after publication in the **Federal Register** of this Third Report and Order."

2. In the second column, paragraph 433, remove "Sections 54.202(a)(6), (d), and (e) and 54.205(c)" and add in their place "Sections 54.202(a)(6), (d), and (e), 54.205(c), and 54.400(l)".

3. In the second column, paragraph 434, add "54.400(f), (j), (m) through (o)," after "54.101".

§ 54.202 [Corrected]

■ 4. On page 33089, in the second column, § 54.202 Additional requirements for Commission designation or eligible telecommunications carriers, in paragraph (d), in the second sentence, remove "should" and add in its place the word "shall".

§ 54.405 [Corrected]

■ 5. On page 33091, in the first column, § 54.405 Carrier obligation to offer Lifeline, in paragraph (e)(3) remove the words "assess or collect" and add in their place the words "assess and collect".

§ 54.408 [Corrected]

■ 6. On page 33092, in the third column, § 54.408 Minimum service standards, in paragraph (f)(1) remove the words "broadband provider" and add in their place the words "broadband Lifeline provider".

■ 7. On page 33092, in the third column, § 54.408 Minimum service standards, in paragraph (f)(2) remove the words "A provider" and add in their place the words "A Lifeline provider".

■ 8. On page 33092, in the third column, § 54.408 Minimum service standards, in paragraph (f)(3) remove the words "broadband provider" and add in their place the words "broadband Lifeline provider".

§ 54.410 [Corrected]

■ 9. On page 33093, in the second column, § 54.410 Subscriber eligibility determination and certification, in paragraph (b)(1)(ii), remove the words "by National Verifier." and add in their place the words "by the National Verifier."

■ 10. On page 33094, in the first column, § 54.410 Subscriber eligibility determination and certification, in paragraph (f)(2)(iii), remove the words "the National Verifier, state Lifeline administrator, or state agency" and add in their place the words "the eligible telecommunications carrier"

■ 11. On page 33094, in the first column, § 54.410 Subscriber eligibility determination and certification, in paragraph (f)(4), remove the words "re-certification or subscribers' Lifeline" and add in their place the words "re-certification of subscribers' Lifeline"

■ 12. On page 33094, in the second column, § 54.410 Subscriber eligibility determination and certification, in paragraph (f)(5), remove the words "state agency's inability" and add in their place the words "state agency that it is unable"

Federal Communications Commission.
Marlene H. Dortch,
Secretary.

[FR Doc. 2016–15194 Filed 7–14–16; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF ENERGY

48 CFR Parts 902, 909, 916, 917, 922, 925, 931, 936, 942, 952, and 970

RIN 1991–AC00

Acquisition Regulation: Technical and Administrative Changes to Department of Energy Acquisition Regulation

AGENCY: Office of Acquisition Management, Department of Energy.

ACTION: Final rule.

SUMMARY: The Department of Energy (DOE) is adopting as final, a rule amending the Department of Energy Acquisition Regulation (DEAR) to make technical and administrative changes to the DEAR, including changes to conform to the Federal Acquisition Regulation (FAR), remove out-of-date coverage, update references, and correct minor errors and omissions.

DATES: *Effective Date:* August 15, 2016.

Applicability Date: This final rule is applicable to solicitations issued on or after the effective date.

FOR FURTHER INFORMATION CONTACT: Lawrence Butler, U.S. Department of Energy, Office of Acquisition Management, MA–611, 1000 Independence Avenue SW., Washington, DC 20585–0121. Telephone: (202) 287–1945. Email: *lawrence.butler@hq.doe.gov.*

SUPPLEMENTARY INFORMATION:

I. Background
II. Summary of Comments and Responses
III. Section-by-Section Analysis
IV. Procedural Requirements
  A. Review Under Executive Order 12866 and 13563
  B. Review Under Executive Order 12988
  C. Review Under the Regulatory Flexibility Act
  D. Review Under the Paperwork Reduction Act
  E. Review Under the National Environmental Policy Act
  F. Review Under Executive Order 13132
  G. Review Under the Unfunded Mandates Reform Act of 1995
  H. Review Under the Treasury and General Government Appropriations Act, 1999
  I. Review Under Executive Order 13211
  J. Review Under the Treasury and General Government Appropriations Act, 2001
  K. Review Under Executive Order 13609
  L. Approval by the Office of the Secretary of Energy
  M. Congressional Notification

I. Background

The DEAR has outdated citations and minor errors of a technical nature. The objective of this final rule is to update the outdated citations and correct the errors and omissions in the existing DEAR to conform to the FAR. None of these changes are substantive or of a nature to cause any significant expense for DOE or its contractors.

II. Summary of Comments and Responses

DOE published a proposed rule at 80 FR 15737 on March 25, 2015; DOE did not receive any comments in response to the proposed rule. DOE made one change in the final rule in part 916. In the proposed rule, DOE proposed to change the title of the NNSA Task Order Ombudsman in Section 916.505, paragraph (b)(6)(i). However, DOE determined that because NNSA gets this authority from the delegations to the Senior Procurement Executive and Head of the Contracting Activity, it is not necessary to include it in the DEAR. Therefore, DOE has removed it from the final rule.

III. Section-by-Section Analysis

DOE amends the DEAR as follows:

Part 902—Definitions of Words and Terms

1. Section 902.101, paragraph (2), is revised to change the title of the National Nuclear Security Administration (NNSA) Senior Procurement Executive (SPE).

Part 909—Contractor Qualifications

2. Section 909.403, paragraphs (1) and (2), are revised to change the title of the NNSA SPE.

Part 916—Types of Contracts

3. Section 916.505, paragraph (b)(6)(i), DOE proposed to change the title of the NNSA Task Order Ombudsman. However, DOE decided to remove the identification of the NNSA Task Order Ombudsman in the final rule because the delegations to the Senior Procurement Executive and the Head of the Contracting Activity allow NNSA to designate a task and delivery order ombudsman.

Part 917—Special Contracting Methods

4. Section 917.602, paragraph (a), is revised to remove language that is no longer needed in the DEAR.

Part 922—Application of Labor Laws to Government Acquisition

5. Section 922.804 is no longer needed in the DEAR and is removed.

Part 925—Foreign Acquisition

6. Section 925.103, paragraph (a), is revised to correct the CFR reference.

7. Section 925.1001, paragraph (b), is revised to change the title of the NNSA SPE.

Part 931—Contract Cost Principles and Procedures

8. Section 931.205–18, paragraph (c)(2), is deleted in its entirety and replaced with a new paragraph (c).

Part 936—Construction and Architect-Engineer Contracts

9. Section 936.202–70 is no longer needed in the DEAR and is removed.

Part 942—Contract Administration and Audit Services

10. Section 942.705–3 is revised to update the circular number and remove the paragraph numbering.

Part 952—Solicitation Provisions and Contract Clauses

11. Section 952.204–2, paragraph (j), is revised to inform contractors of the format for submitting Foreign Ownership, Control or Influence (FOCI) information. Paragraph (h)(2)(vi), is revised to remove Contractor requirement for submitting in writing information to the head of the cognizant local DOE Security Office concerning each uncleared applicant or uncleared employee who is selected for a position requiring an access authorization.

12. Section 952.204–73, paragraph (a), is revised to inform contractors of the format for submitting FOCI information.

13. Section 952.236–72 is no longer needed in the DEAR and is removed.

14. Section 952.250–70, paragraph (d)(1), is revised to raise the threshold as required by the Energy Policy Act of 2005.

Part 970—DOE Management and Operating Contracts

15. Section 970.5215–3 is revised to update the Order number.

16. Section 970.5223–1 is revised to correct the prescription.

17. Section 970.5244–1, paragraph (f) is revised to reflect threshold increase in 48 CFR 28.102–2. Paragraph (g) is revised to reflect the threshold increase in DOE's class deviation for DEAR 970.5244–1.

18. Section 970.5245–1, Alternate I, paragraph (j)(3), is revised to update the Order number and to add language that clarifies the sentence.

IV. Procedural Requirements

A. Review Under Executive Order 12866 and 13563

This regulatory action has been determined not to be a ''significant regulatory action'' under Executive Order 12866, ''Regulatory Planning and Review,'' 58 FR 51735 (October 4, 1993). Accordingly, this final rule is not subject to review under that Executive Order by the Office of Information and Regulatory Affairs (OIRA) of the Office of Management and Budget (OMB).

DOE has also reviewed this regulation pursuant to Executive Order 13563, issued on January 18, 2011 (76 FR 3281 (Jan. 21, 2011)). Executive Order 13563 is supplemental to and explicitly reaffirms the principles, structures, and definitions governing regulatory review established in Executive Order 12866. To the extent permitted by law, agencies are required by Executive Order 13563 to: (1) Propose or adopt a regulation only upon a reasoned determination that its benefits justify its costs (recognizing that some benefits and costs are difficult to quantify); (2) tailor regulations to impose the least burden on society, consistent with obtaining regulatory objectives, taking into account, among other things, and to the extent practicable, the costs of cumulative regulations; (3) select, in choosing among alternative regulatory approaches, those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity); (4) to the extent feasible, specify performance objectives, rather than specifying the behavior or manner of compliance that regulated entities must adopt; and (5) identify and assess available alternatives to direct regulation, including providing economic incentives to encourage the desired behavior, such as user fees or marketable permits, or providing information upon which choices can be made by the public.

DOE emphasizes as well that Executive Order 13563 requires agencies to use the best available techniques to quantify anticipated present and future benefits and costs as accurately as possible. In its guidance, the Office of Information and Regulatory Affairs has emphasized that such techniques may include identifying changing future compliance costs that might result from technological innovation or anticipated behavioral changes. DOE believes that this final rule is consistent with these principles, including the requirement that, to the extent permitted by law, agencies adopt a regulation only upon a reasoned determination that its benefits justify its costs and, in choosing among alternative regulatory approaches, those approaches maximize net benefits.

B. Review Under Executive Order 12988

With respect to the review of existing regulations and the promulgation of new regulations, section 3(a) of Executive Order 12988, ''Civil Justice Reform,'' 61 FR 4729 (February 7, 1996), imposes on Executive agencies the general duty to adhere to the following requirements: (1) Eliminate drafting errors and ambiguity; (2) write regulations to minimize litigation; and (3) provide a clear legal standard for affected conduct rather than a general standard and promote simplification and burden reduction.

With regard to the review required by section 3(a), section 3(b) of Executive Order 12988 specifically requires that Executive agencies make every reasonable effort to ensure that the regulation: (1) Clearly specifies the preemptive effect, if any; (2) clearly specifies any effect on existing Federal law or regulation; (3) provides a clear legal standard for affected conduct while promoting simplification and burden reduction; (4) specifies the retroactive effect, if any; (5) adequately defines key terms; and (6) addresses other important issues affecting clarity and general draftsmanship under any guidelines issued by the United States Attorney General. Section 3(c) of Executive Order 12988 requires Executive agencies to review regulations in light of applicable standards in section 3(a) and section 3(b) to determine whether they are met or if it is unreasonable to meet one or more of them. DOE has completed the required review and determined that, to the extent permitted by law, this final rule meets the relevant standards of Executive Order 12988.

C. Review Under the Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires preparation of an initial regulatory flexibility analysis for any rule that by law must be proposed for public comment, unless the agency certifies that the rule, if promulgated, will not have a significant economic impact on a substantial number of small entities. As required by Executive Order 13272, "Proper Consideration of Small Entities in Agency Rulemaking," 67 FR 53461 (August 16, 2002), DOE published procedures and policies on February 19, 2003, to ensure that the potential impacts of its rules on small entities are properly considered during the rulemaking process (68 FR 7990). DOE has made its procedures and policies available on the Office of General Counsel's Web site at *http://www.energy.gov/gc/office-general-counsel.*

This final rule is to amend the DEAR to make technical and administrative changes as described in the summary. These changes are technical/minor in nature; therefore, DOE certifies that this rule would not have a significant economic impact on small entities because no substantive rights or obligations are altered by the amendment. Consequently, DOE did not prepare a regulatory flexibility analysis for this rulemaking.

D. Review Under the Paperwork Reduction Act

This final rule does not impose a collection of information requirement subject to the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* Existing burdens associated with the collection of certain contractor data under the DEAR have been cleared under OMB control number 1910–4100, with an expiration date of December 31, 2017.

E. Review Under the National Environmental Policy Act

DOE has concluded that promulgation of this final rule falls into a class of actions which would not individually or cumulatively have significant impact on the human environment, as determined by DOE's regulations (10 CFR part 1021, subpart D) implementing the National Environmental Policy Act (NEPA) of 1969 (42 U.S.C. 4321 *et seq.*). Specifically, this final rule is categorically excluded from NEPA review because the amendments to the DEAR are strictly procedural (categorical exclusion A6). Therefore, this final rule does not require an environmental impact statement or environmental assessment pursuant to NEPA.

F. Review Under Executive Order 13132

Executive Order 13132, 64 FR 43255 (August 4, 1999), imposes certain requirements on agencies formulating and implementing policies or regulations that preempt State law or that have federalism implications. Agencies are required to examine the constitutional and statutory authority supporting any action that would limit the policymaking discretion of the States and carefully assess the necessity for such actions. The Executive Order requires agencies to have an accountability process to ensure meaningful and timely input by state and local officials in the development of regulatory policies that have federalism implications.

On March 14, 2000, DOE published a statement of policy describing the intergovernmental consultation process it will follow in the development of such regulations (65 FR 13735). DOE has examined the final rule and has determined that it does not preempt State law and does not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. No further action is required by Executive Order 13132.

G. Review Under the Unfunded Mandates Reform Act of 1995

The Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) generally requires a Federal agency to perform a written assessment of costs and benefits of any rule imposing a Federal mandate with costs to State, local or tribal governments, or to the private sector, of $100 million or more. This rulemaking does not impose a Federal mandate on State, local or tribal governments or on the private sector.

H. Review Under the Treasury and General Government Appropriations Act, 1999

Section 654 of the Treasury and General Government Appropriations Act, 1999 (Pub. L. 105–277), requires Federal agencies to issue a Family Policymaking Assessment for any rulemaking or policy that may affect family well-being. This rulemaking will have no impact on the autonomy or integrity of the family as an institution. Accordingly, DOE has concluded that it is not necessary to prepare a Family Policymaking Assessment.

I. Review Under Executive Order 13211

Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use, 66 FR 28355 (May 22, 2001), requires Federal agencies to prepare and submit to Office of Information and Regulatory Affairs (OIRA), of the Office of Management and Budget (OMB), a Statement of Energy Effects for any significant energy action. A "significant energy action" is defined as any action by an agency that promulgates or is expected to lead to promulgation of a final rule, and that: (1) Is a significant regulatory action under Executive Order 12866, or any successor order; (2) is likely to have a significant adverse effect on the supply, distribution, or use of energy; or (3) is designated by the Administrator of OIRA as a significant energy action. For any significant energy action, the agency must give a detailed statement of any adverse effects on energy supply, distribution, or use should the proposal be implemented, and of reasonable alternatives to the action and their expected benefits on energy supply, distribution, and use. This final rule is not a significant energy action.

Accordingly, DOE has not prepared a Statement of Energy Effects.

J. Review Under the Treasury and General Government Appropriations Act, 2001

The Treasury and General Government Appropriations Act, 2001 (44 U.S.C. 3516, note) provides for agencies to review most disseminations of information to the public under guidelines established by each agency pursuant to general guidelines issued by OMB. OMB's guidelines were published at 67 FR 8452 (February 22, 2002), and DOE's guidelines were published at 67 FR 62446 (October 7, 2002). DOE has reviewed this final rule under the OMB and DOE guidelines and has concluded that it is consistent with applicable policies in those guidelines.

K. Review Under Executive Order 13609

Executive Order 13609 of May 1, 2012, "Promoting International Regulatory Cooperation," requires that, to the extent permitted by law and consistent with the principles and requirements of Executive Order 13563 and Executive Order 12866, each Federal agency shall:

(a) If required to submit a Regulatory Plan pursuant to Executive Order 12866, include in that plan a summary of its international regulatory cooperation activities that are reasonably anticipated to lead to significant regulations, with an explanation of how these activities advance the purposes of Executive Order 13563 and this order;

(b) Ensure that significant regulations that the agency identifies as having significant international impacts are designated as such in the Unified Agenda of Federal Regulatory and Deregulatory Actions, on *RegInfo.gov,* and on *Regulations.gov;*

(c) In selecting which regulations to include in its retrospective review plan, as required by Executive Order 13563, consider:

(i) Reforms to existing significant regulations that address unnecessary differences in regulatory requirements between the United States and its major trading partners, consistent with section 1 of this order, when stakeholders provide adequate information to the agency establishing that the differences are unnecessary; and

(ii) Such reforms in other circumstances as the agency deems appropriate; and

(d) For significant regulations that the agency identifies as having significant international impacts, consider, to the extent feasible, appropriate, and consistent with law, any regulatory approaches by a foreign government that the United States has agreed to consider under a regulatory cooperation council work plan.

DOE has reviewed this final rule under the provisions of Executive Order 13609 and determined that the rule complies with all requirements set forth in the order.

L. Approval by the Office of the Secretary of Energy

Issuance of this final rule has been approved by the Office of the Secretary of Energy.

M. Congressional Notification

As required by 5 U.S.C. 801, DOE will report to Congress on the promulgation of this rule prior to its effective date. The report will state that it has been determined that the rule is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 48 CFR Parts 902, 909, 916, 917, 922, 925, 931, 936, 942, 952 and 970

Government procurement.

Issued in Washington, DC, on July 7, 2016.

John R. Bashista,

Director, Office of Acquisition Management, Department of Energy.

Joseph Waddell,

Senior Procurement Executive and Deputy Associate Administrator National Nuclear Security Administration, Office of Acquisition and Project Management.

For the reasons set out in the preamble, the Department of Energy amends chapter 9 of title 48 of the Code of Federal Regulations as set forth below.

Title 48—Federal Acquisition Regulations System

■ 1. The authority citation for parts 902, 903, 916, 917, 922, 925, 931, 936 and 942 continues to read as follows:

Authority: 42 U.S.C. 7101 *et seq.* and 50 U.S.C. 2401 *et seq.*

PART 902—DEFINITIONS OF WORDS AND TERMS

902.101 [Amended]

■ 2. Section 902.101 is amended in the definition of "Senior Procurement Executive" by removing "Director, Office of Acquisition and Supply Management" and adding in its place "Deputy Associate Administrator for Acquisition and Project Management".

PART 909—CONTRACTOR QUALIFICATIONS

909.403 [Amended]

■ 3. Section 909.403 is amended in paragraphs (1) and (2) by removing "Director, Office of Acquisition and Supply Management" and adding in its place "Deputy Associate Administrator for Acquisition and Project Management".

PART 916—TYPES OF CONTRACTS

916.505 [Amended]

■ 4. Section 916.505 is amended in paragraph (b)(6)(i) by removing the second sentence.

PART 917—SPECIAL CONTRACTING METHODS

917.602 [Amended]

■ 5. Section 917.602 is amended in paragraph (a) by removing ", Deputy Secretary or Under Secretary".

PART 922—APPLICATION OF LABOR LAWS TO GOVERNMENT ACQUISITION

922.804 [Removed and Reserved]

■ 6. Section 922.804 is removed and reserved.

PART 925—FOREIGN ACQUISITION

■ 7. Section 925.103 is amended by removing paragraph (a) and revising paragraph (b)(2).

The revision reads as follows:

925.103 Exceptions.

(b) *Nonavailabilty*—(2)(i) *Individual determinations.* Contracting officers may make the determination required by 48 CFR 25.103(b)(2)(i), provided such determination is factually supported in writing. If the contract is estimated to exceed $1 million, the Head of the Contracting Activity must approve the determination.

(ii) Proposals to add an article to the list of nonavailable articles at 48 CFR 25.104, with appropriate justifications, must be submitted for approval by the Senior Procurement Executive and submission to the appropriate council.

925.1001 [Amended]

■ 8. Section 925.1001 is amended in paragraph (b) by removing "Director, Office of Acquisition and Supply Management" and adding in its place "Deputy Associate Administrator for Acquisition and Project Management".

PART 931—CONTRACT COST PRINCIPLES AND PROCEDURES

■ 9. Section 931.205–18 is revised to read as follows:

931.205–18 Independent research and development (IR&D) and bid and proposal (B&P) costs.

(c) In addition to all the other FAR requirements for allowability of IR&D costs, costs for IR&D are allowable under DOE contracts to the extent: They are not otherwise unallowable; and they have potential benefit or relationship to the DOE program. The term ''DOE program'' encompasses the DOE total mission and its objectives. In addition to all the other FAR requirements for allowability of B&P costs, costs for B&P are allowable under DOE contracts to the extent they are not otherwise unallowable.

PART 936—CONSTRUCTION AND ARCHITECT-ENGINEER CONTRACTS

936.202–70 [Removed and Reserved]

■ 10. Section 936.202–70 is removed and reserved.

PART 942—CONTRACT ADMINISTRATION AND AUDIT SERVICES

942.705–3 [Amended]

■ 11. Section 942.705–3 is amended by:
■ a. Removing the paragraph designation ''(a)(2)''; and
■ b. Removing ''A–88'' and adding in its place ''A–21''.

PART 952—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 12. The authority citation for part 952 continues to read as follows:

Authority: 42 U.S.C. 2201; 2282a; 2282b; 2282c; 42 U.S.C. 7101 *et seq.;* 50 U.S.C. 2401 *et seq.*

■ 13. Section 952.204–2 is amended by:
■ a. Revising the section heading;
■ b. Revising the clause heading and clause date; and
■ c. Revising paragraphs (h)(2)(vi) introductory text and (j)(1).

The revisions read as follows:

952.204–2 Security requirements.

* * * * *

SECURITY REQUIREMENTS (Aug. 2016)

* * * * *

(h) * * *

(2) * * *

(vi) The Contractor must maintain a record of information concerning each uncleared applicant or uncleared employee who is selected for a position requiring an access authorization. Upon request only, the following information will be furnished to the head of the cognizant local DOE Security Office:

* * * * *

(j) *Foreign ownership, control, or influence.* (1) The Contractor shall immediately provide the cognizant security office written notice of any change in the extent and nature of foreign ownership, control or influence over the Contractor which would affect any answer to the questions presented in the Standard Form (SF) 328, *Certificate Pertaining to Foreign Interests,* executed prior to award of this contract. The Contractor will submit the Foreign Ownership, Control or Influence (FOCI) information in the format directed by DOE. When completed the Contractor must print and sign one copy of the SF 328 and submit it to the Contracting Officer. In addition, any notice of changes in ownership or control which are required to be reported to the Securities and Exchange Commission, the Federal Trade Commission, or the Department of Justice, shall also be furnished concurrently to the Contracting Officer.

* * * * *

■ 14. Section 952.204–73 is amended by revising the date of the clause and paragraph (a)(1) to read as follows:

952.204–73 Facility clearance.

* * * * *

FACILITY CLEARANCE (Aug. 2016)

* * * * *

(a) *Use of Certificate Pertaining to Foreign Interests, Standard Form 328.* (1) The contract work anticipated by this solicitation will require access to classified information or special nuclear material. Such access will require a Facility Clearance for the Contractor's organization and access authorizations (security clearances) for Contractor personnel working with the classified information or special nuclear material. To obtain a Facility Clearance the Contractor must submit the Standard Form 328, Certificate Pertaining to Foreign Interests, and all required supporting documents to form a complete Foreign Ownership, Control or Influence (FOCI) Package. The Contractor will submit the Foreign Ownership, Control or Influence (FOCI) information in the format directed by DOE. When completed the Contractor must print and sign one copy of the SF 328 and submit it to the Contracting Officer.

* * * * *

952.236–72 [Removed and Reserved]

■ 15. Section 952.236–72 is removed and reserved.

952.250–70 [Amended]

■ 16. Section 952.250–70 is amended by:
■ a. Revising the date of the clause; and
■ b. Removing in paragraph (d)(1), ''$100 million'' and adding in its place ''$500 million''.

The revision reads as follows:

952.250–70 Nuclear hazards indemnity agreement.

* * * * *

NUCLEAR HAZARDS INDEMNITY AGREEMENT (Aug. 2016)

* * * * *

PART 970—DOE MANAGEMENT AND OPERATING CONTRACTS

■ 17. The authority citation for part 970 continues to read as follows:

Authority: 42 U.S.C. 2201; 2282a; 2282b; 2282c; 42 U.S.C. 7101 *et seq.;* 50 U.S.C. 2401 *et seq.*

970.5215–3 [Amended]

■ 18. Section 970.5215–3, paragraphs (c)(1)(i) and (c)(2)(i) are amended by removing ''DOE Order 225.1A'' and adding in its place ''DOE Order 225.1B, or successor version''.

970.5223–1 [Amended]

■ 19. Section 970.5223–1 is amended by removing ''970.2303–3(b)'' in the clause introductory text and adding in its place, ''970.2303–3(a)''.
■ 20. Section 970.5244–1 is amended by:
■ a. Revising the clause date;
■ b. Removing in paragraphs (f)(1) and (2) ''$100,000'' and adding in its place ''$150,000''; and
■ c. Removing in paragraph (g) ''$100,000'' in both occurrences and adding in each place ''$500,000''.

The revision reads as follows:

970.5244–1 Contractor purchasing system.

* * * * *

CONTRACTOR PURCHASING SYSTEM (Aug. 2016)

* * * * *

■ 21. Section 970.5245–1 is amended by:
■ a. Revising the clause date;
■ b. Revising Alternate I heading and date; and
■ c. Removing in Alternate I paragraph (j)(3) ''Major System Acquisition or Major Project'' and adding in its place ''Major System Project'' and removing ''DOE Order 4700.1'' and adding in its place ''DOE Order 413.3B, or successor version''.

The revisions read as follows:

970.5245–1 Property.

* * * * *

PROPERTY (Aug. 2016)

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Alternate I (Aug. 2016).

* * * * *

[FR Doc. 2016–16768 Filed 7–14–16; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

49 CFR Part 8

RIN 2105–AE50

Classified Information: Classification/ Declassification/Access; Authority To Classify Information (RRR)

AGENCY: Office of the Secretary of Transportation (OST), U.S. Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: This final rule updates the regulations regarding classified information to reflect changes in organizational structure, update the legal authorities, incorporate new references, and refer historical researchers and former Presidential appointees to Executive Order 13526.

DATES: This final rule is effective July 15, 2016.

FOR FURTHER INFORMATION CONTACT: Joan Harris, Associate Director, Office of Security, 202–366–1827, or electronically at *joan.harris@dot.gov.* You may also contact David Meade, Senior Security Specialist, Office of Security, 202–366–8891, or electronically at *david.meade@dot.gov.*

SUPPLEMENTARY INFORMATION: A 2011 DOT final rule (76 FR 19707) announced changes regarding the authority to classify information, but did not update other parts of the rule. As a result, the Department's regulations at 49 CFR part 8 need to be updated. This final rule makes the following corrections: Executive Order 12958, "Classified National Security Information," has been replaced by Executive Order 13526, so references to the outdated Executive Order have been removed. The "Interagency Classification Review Committee" is now the Interagency Security Classification Appeals Panel. As a result of reorganizations after the September 11, 2001, terrorist attacks, the U.S. Coast Guard is no longer a part of DOT, so references to that agency as a departmental component have been removed, and a representative from the Federal Highway Administration replaces the U.S. Coast Guard's representative on the Department's Personnel Security Review Board. This final rule also updates the names of some departmental offices, which have changed.

Section 8.19, which contained detailed instructions for submitting and processing requests for classification challenges and mandatory classification reviews, is also eliminated because of inconsistencies with the current regulations at 32 CFR 2001. Sections 8.15 (Mandatory review for classification) and 8.17 (Classification challenges) have been rewritten to cite the appropriate sections of 32 CFR 2001 regarding such requests.

The detailed instructions in Section 8.29, Access by historical researchers and former Presidential appointees, have been eliminated because they were outdated. Instead, the instructions have been replaced with a reference to Executive Order 13526, which describes the conditions that qualify such persons for access, and Executive Order 12968 which provides general guidelines for access to classified information.

This final rule is exempt from Administrative Procedure Act (APA) notice-and-comment requirements. This final rule does not affect any substantive changes to the regulations or alter any existing compliance obligations. This final rule would only make technical corrections to part 8 by correcting outdated references without affecting the substance of the underlying rulemaking document. For the reasons stated above, notice and comment procedures are unnecessary within the meaning of the APA. See 5 U.S.C. 553(b)(3)(B).

The Department finds good cause for this final rule to become effective immediately under 5 U.S.C. 553(d)(1). This final rule is only removing outdated, obsolete, and inconsistent language in the regulations without altering any existing compliance obligations contained in the current regulations. Since this final rule is nonsubstantive and will not affect any regulated entity's compliance with the current regulations, the Department finds good cause for it to become effective immediately.

Regulatory Analyses and Notices

A. Executive Order 12866 and DOT Regulatory Policies and Procedures

The DOT has determined that this action is not a significant regulatory action within the meaning of Executive Order 12866, and within the meaning of DOT's regulatory policies and procedures. Since this rulemaking merely removes obsolete and inconsistent language and makes editorial corrections and does not have any substantive impact on the regulated community, DOT anticipates that this rulemaking will have no economic impact.

Additionally, this action fulfills the principles of Executive Order 13563, specifically those relating to retrospective analyses of existing rules. This rule is being issued as a result of the reviews of existing regulations that the Department periodically conducts. In addition, these changes will not interfere with any action taken or planned by another agency and would not materially alter the budgetary impact of any entitlements, grants, user fees, or loan programs. Consequently, a full regulatory evaluation is not necessary.

B. Executive Order 13132

Executive Order 13132 requires agencies to ensure meaningful and timely input by State and local officials in the development of regulatory policies that may have a substantial, direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. This action has been analyzed in accordance with the principles and criteria contained in Executive Order 13132, dated August 4, 1999, and the DOT has determined that this action would not have a substantial direct effect or sufficient federalism implications on the States. The DOT has also determined that this action would not preempt any State law or regulation or affect the States' ability to discharge traditional State governmental functions. Therefore, consultation with the States is not necessary.

C. Executive Order 13175

The DOT has analyzed this action under Executive Order 13175, dated November 6, 2000, and believes that the action would not have substantial direct effects on one or more Indian tribes, would not impose substantial direct compliance costs on Indian tribal governments, and would not preempt tribal laws. This final rule merely updates outdated terminology, and removes inconsistent language relating to compliance with the Department's classified information regulations. It does not impose any new requirements on Indian tribal governments. Therefore, a tribal summary impact statement is not required.

D. Regulatory Flexibility Act

Since notice-and-comment rulemaking is not necessary for this rule, the provisions of the Regulatory Flexibility Act (Pub. L. 96–354, 5 U.S.C.

601–612) do not apply. However, the DOT has evaluated the effects of this action on small entities and has determined that the action would not have a significant economic impact on a substantial number of small entities. The rule removes obsolete guidance language and updates outdated terminology and, therefore, does not add to or alter any existing obligations.

E. Paperwork Reduction Act

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501, *et seq.*), Federal agencies must obtain approval from the Office of Management and Budget for each collection of information they conduct, sponsor, or require through regulations. The DOT has analyzed this final rule under the PRA and has determined that this rule does not contain collection of information requirements for the purposes of the PRA.

F. Unfunded Mandates Reform Act

This final rule would not impose unfunded mandates, as defined by the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4, 109 Stat. 48, March 22, 1995), as it will not result in the expenditure by State, local, or tribal governments, in the aggregate, or by the private sector, of $148.1 million or more in any one year (2 U.S.C. 1532).

G. National Environmental Policy Act

The agency has analyzed the environmental impacts of this proposed action pursuant to the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321 *et seq.*) and has determined that it is categorically excluded pursuant to DOT Order 5610.1C, Procedures for Considering Environmental Impacts (44 FR 56420, Oct. 1, 1979). Categorical exclusions are actions identified in an agency's NEPA implementing procedures that do not normally have a significant impact on the environment and therefore do not require either an environmental assessment (EA) or environmental impact statement (EIS). See 40 CFR 1508.4. In analyzing the applicability of a categorical exclusion, the agency must also consider whether extraordinary circumstances are present that would warrant the preparation of an EA or EIS. Id. Paragraph 3.c.5 of DOT Order 5610.1C incorporates by reference the categorical exclusions for all DOT Operating Administrations. This action is covered by the categorical exclusion listed in the Federal Highway Administration's implementing procedures, "[p]romulgation of rules, regulations, and directives." 23 CFR 771.117(c)(20). The purpose of this rulemaking is to make editorial corrections and remove obsolete and inconsistent language in the Department's classified information regulations. The agency does not anticipate any environmental impacts, and there are no extraordinary circumstances present in connection with this rulemaking.

List of Subjects in 49 CFR Part 8

Classified Information (Government agencies), Classification/Declassification/Access (Government agencies).

The Final Rule

For the reasons set forth in the preamble, OST amends 49 CFR part 8 as follows:

PART 8—[AMENDED]

■ 1. The authority citation for part 8 is revised to read as follows:

Authority: E.O. 10450, 18 FR 2489, 3 CFR, 1949–1953 Comp., p. 936, amended by E.O. 10491, 18 FR 6583, 3 CFR, 1949–1953 Comp., p. 973, E.O. 10531, 19 FR 3069, 3 CFR, 1949–1953 Comp., p. 973, E.O. 10548, 19 FR 4871, 3 CFR, 1954–1958 Comp., p. 200, E.O. 10550, 19 FR 4981, 3 CFR, 1954–1958 Comp., p. 200, E.O. 11605, 20 FR 2747, 3 CFR, 1971–1975 Comp., p. 580, E.O. 11785, 39 FR 20053, 3 CFR, 1971–1975 Comp., p. 874, E.O. 12107, 44 FR 1055, 3 CFR, 1978 Comp., p. 266; E.O. 12829, 58 FR 3479, 3 CFR, 1993 Comp., p. 570, amended by E.O. 12885, 58 FR 65863, 3 CFR, 1993 Comp., p. 684; E.O. 13526, 75 FR 707, 3 CFR, 2010 Comp., p. 298; E.O. 12968, 3 CFR, 1995 Comp., p. 391, amended by E.O. 13467, 73 FR 38103, 3 CFR, 2009 Comp., p. 196.

■ 2. Part 8 is amended by:

■ a. Removing "Director of Security and Administrative Management" and adding in its place "Director of Security" wherever it appears; and

■ b. Removing "Executive Order 12958" and adding in its place "Executive Order 13526" wherever it appears.

Subpart A—General

■ 3. Section 8.1 is revised to read as follows:

§ 8.1 Scope.

This part sets forth procedures for the classification, declassification, and availability of information that must be protected in the interest of national security, in implementation of Executive Order 13526 of December 29, 2010, "Classified National Security Information;" and for the review of decisions to revoke, or not to issue, national security information clearances, or to deny access to classified information, under Executive Order 12968 of August 2, 1995, "Access to National Security Information," as amended by Executive Order 13467 of June 30, 2008, "Reforming Processes Related to Suitability for Government Employment, Fitness for Contractor Employees, and Eligibility for Access to Classified National Security Information."

■ 4. In § 8.5, add a definition for "Authorized holder" and revise the definitions of "Clearance", "Damage to the national security", "Mandatory declassification", and "Original classification authority" to read as follows:

§ 8.5 Definitions.

* * * * *

Authorized holder is any individual who has been granted access to specific classified information in accordance with Executive Order 13526 or any successor order.

* * * * *

Clearance means that an individual is eligible, under the standards of Executive Orders 10450, 12968, 13467, and appropriate DOT regulations, for access to classified information.

Damage to the national security means harm to the national defense or foreign relations of the United States from the unauthorized disclosure of information, taking into consideration such aspects of the information as the sensitivity, value, utility, and provenance of that information.

* * * * *

Mandatory declassification review means the review for declassification of classified information in response to a request for declassification that meets the requirements of section 3.5 of Executive Order 13526.

* * * * *

Original classification authority means an individual authorized in writing, either by the President, the Vice President, or by agency heads or other officials designated by the President, to classify information in the first instance.

■ 5. In § 8.7, paragraph (a) is revised to read as follows:

§ 8.7 Spheres of responsibility.

(a) Pursuant to section 5.4(d) of Executive Order 13526, and to section 6.1 of Executive Order 12968, the Assistant Secretary for Administration is hereby designated as the senior agency official of the Department of Transportation with assigned responsibilities to assure effective compliance with and implementation of Executive Order 13526, Executive Order 12968, Office of Management and

Budget Directives, the regulations in this part, and related issuances.

* * * * *

Subpart B—Classification/ Declassification of Information

■ 6. In § 8.9, paragraphs (a) introductory text and (b) are revised to read as follows:

§ 8.9 Information Security Review Committee.

(a) The Department of Transportation Information Security Review Committee has the authority to:

* * * * *

(b) The Information Security Review Committee will be composed of the Assistant Secretary for Administration, who will serve as Chair; the General Counsel; and the Director of Security. When matters affecting a particular Departmental component are at issue, the Associate Administrator for Administration for that component (or for the Federal Aviation Administration, the Associate Administrator for Security and Hazardous Materials Safety) will participate as an ad hoc member, together with the Chief Counsel of that component. Any regular member may designate a representative with full power to serve in his/her place.

* * * * *

■ 7. In § 8.11, paragraphs (a), (b)(1) and (2), and (c) are revised to read as follows:

§ 8.11 Authority to classify information.

(a) Presidential Order of December 29, 2009, "Original Classification Authority" confers upon the Secretary of Transportation the authority to originally classify information as SECRET or CONFIDENTIAL with further authorization to delegate this authority.

(b) * * *

(1) *Office of the Secretary of Transportation.* The Deputy Secretary; Assistant Secretary for Administration; Director of Intelligence, Security and Emergency Response; Director of Security.

(2) *Federal Aviation Administration.* Administrator; Associate Administrator for Security and Hazardous Materials Safety.

* * * * *

(c) Although the delegations of authority set out in paragraph (b) of this section are expressed in terms of positions, the authority is personal and is invested only in the individual occupying the position. The authority may not be exercised "by direction of" a designated official. The formal appointment or assignment of an individual to one of the identified positions or a designation in writing to act in the absence of one of these officials, however, conveys the authority to originally classify information as SECRET or CONFIDENTIAL.

* * * * *

■ 8. Revise § 8.15 to read as follows:

§ 8.15 Mandatory review for classification.

(a) Mandatory declassification review requests will be processed in accordance with 32 CFR 2001.33.

(b) Except as provided in paragraph b of section 3.5 of Executive Order 13526, all information classified by the Department of Transportation under Executive Order 13526 or predecessor orders shall be subject to a review for declassification if:

(1) The request for review describes the information with sufficient specificity to enable its location with a reasonable amount of effort;

(2) The information has not been reviewed for declassification within the prior two years. If the information has been reviewed within the prior two years, or the information is the subject of pending litigation, the requestor will be informed of this fact, and of the Department's decision not to declassify the information and of his/her right to appeal the Department's decision not to declassify the information to the Interagency Security Classification Appeals Panel (ISCAP);

(3) The document or material containing the information responsive to the request is not contained within an operational file exempted from search and review, publication, and disclosure under 5 U.S.C. 552 in accordance with law; and

(4) The information is not the subject of pending litigation.

(c) All information reviewed for declassification because of a mandatory review will be declassified if it does not meet the standards for classification in Executive Order 13526. The information will then be released unless withholding is otherwise authorized and warranted under applicable law.

(d) Mandatory declassification review requests for information that has been classified by the Department of Transportation may be addressed to the Director of Security, U.S. Department of Transportation, 1200 New Jersey Avenue, Washington, DC 20590. The Director will forward the request to the appropriate Departmental Original Classification Authority for processing.

(e) Denied requests may be appealed to the DOT Information Security Review Committee (DISRC) through the Director of Security within 60 days of receipt of the denial. If the DISRC upholds the denial, it will inform the requestor of his or her final appeal rights to the ISCAP.

■ 9. Revise § 8.17 to read as follows:

§ 8.17 Classification challenges.

(a) Authorized holders of information classified by the Department of Transportation who, in good faith, believe that its classification status is improper are encouraged and expected to challenge the classification status of the information before the Original Classification Authority (OCA) having jurisdiction over the information. A formal challenge must be in writing, but need not be any more specific than to question why information is or is not classified, or is classified at a certain level.

(b) Classification challenges to DOT information must be addressed to the DOT Original Classification Authority (OCA) who is responsible for the information. If unsure of the OCA, address the challenge to the DOT Director of Security.

(c) Classification challenges will be processed according to 32 CFR 2001.14.

§ 8.19 [Removed and Reserved]

■ 10. Remove and reserve § 8.19.

§ 8.21 [Amended]

■ 11. Amend § 8.21 by removing "8.13," and the comma following "8.15", and by removing the word "agency" and adding "component" in its place.

§ 8.23 [Amended]

■ 12. Amend § 8.23 as follows:

■ a. In paragraph (a) by adding an "s" to the word "function";

■ b. In paragraph (b) by removing the word "a" and adding in its place the word "another" in the first sentence and by adding the words "at a lower level" after the word "resolved" in the last sentence;

■ c. In paragraph (c) by adding ", directives issued pursuant to Executive Order 13526," after the words "Executive Order 13526" in the first sentence and in the second sentence by removing the words "in NARA" and adding in their place "into the National Archives"; and

■ d. In paragraph (d) by removing the words "of this part for automatic declassification" at the end of the first sentence, and adding in their place "for automatic declassification in section 3.3 of Executive Order 13526 and its implementing directives".

Subpart C—Access to Information

■ 13. 13. In § 8.25, revise paragraphs (a) introductory text and (b)(1) through (4) and add paragraph (b)(5) to read as follows:

§ 8.25 Personnel Security Review Board.

(a) The Department of Transportation Personnel Security Review Board will, on behalf of the Secretary of Transportation (except in any case in which the Secretary personally makes the decision), make the administratively final decision on an appeal arising in any part of the Department from:

* * * * *

(b) * * *

(1) Two persons appointed by the Assistant Secretary for Administration: One from the Office of Human Resource Management, and one, familiar with personnel security adjudication, from the Office of Security, who will serve as Chair;

(2) One person appointed by the General Counsel, who, in addition to serving as a member of the Board, will provide to the Board whatever legal services it may require;

(3) One person appointed by the Administrator of the Federal Aviation Administration; and

(4) One person appointed by the Administrator of the Federal Highway Administration.

(5) Any member may designate a representative, meeting the same criteria as the member, with full power to serve in his/her place.

* * * * *

■ 14. Section 8.29 is revised to read as follows:

§ 8.29 Access by historical researchers and former Presidential appointees.

Access to classified information may be granted to historical researchers and former Presidents and Vice-Presidents and their appointees as outlined in Executive Order 13526 or its successor order. The general guidelines for access to classified information are contained in Executive Order 12968.

■ 15. In § 8.31, amend paragraph (b) by adding the word "an" between "into agreement" in the first sentence and by removing the last three sentences and adding a new sentence in their place.

The addition reads as follows:

§ 8.31 Industrial security.

* * * * *

(b) * * * Specifically, this regulation is DOD 5220.22–M, National Industrial Security Program Operating Manual, and is effective within the Department of Transportation. Appropriate security staff, project personnel, and contracting officers must assure that actions required by the regulation are taken.

Issued in Washington, DC, on July 5, 2016, under authority delegated in 49 CFR 1.27(c).

Molly J. Moran,

Acting General Counsel.

[FR Doc. 2016–16565 Filed 7–14–16; 8:45 am]

BILLING CODE 4910–9X–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 300

[Docket No. 160205084–6510–02]

RIN 0648–XE719

Western and Central Pacific Fisheries for Highly Migratory Species; 2016 Bigeye Tuna Longline Fishery Closure

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule; fishery closure.

SUMMARY: NMFS is closing the U.S. pelagic longline fishery for bigeye tuna in the western and central Pacific Ocean because the fishery has reached the 2016 catch limit. This action is necessary to ensure compliance with NMFS regulations that implement decisions of the Western and Central Pacific Fisheries Commission (WCPFC).

DATES: Effective 12:01 a.m. local time July 22, 2016, through December 31, 2016.

ADDRESSES: NMFS prepared a plain language guide and frequently asked questions that explain how to comply with this rule; both are available at *https://www.regulations.gov/docket?D=NOAA-NMFS-2016-0091.*

FOR FURTHER INFORMATION CONTACT: Ariel Jacobs, NMFS Pacific Islands Region, 808–725–5182.

SUPPLEMENTARY INFORMATION: Pelagic longline fishing in the western and central Pacific Ocean is managed, in part, under the Western and Central Pacific Fisheries Convention Implementation Act (Act). Regulations governing fishing by U.S. vessels in accordance with the Act appear at 50 CFR part 300, subpart O.

NMFS established a calendar year 2016 limit of 3,554 metric tons (mt) of bigeye tuna (*Thunnus obesus*) that may be caught and retained in the U.S. pelagic longline fishery in the area of application of the Convention on the Conservation and Management of Highly Migratory Fish Stocks in the Western and Central Pacific Ocean (Convention Area) (81 FR 41239, June 24, 2016). NMFS monitored the retained catches of bigeye tuna using logbook data submitted by vessel captains and other available information, and determined that the 2016 catch limit would be reached by July 22, 2016.

In accordance with 50 CFR 300.224(e), this rule serves as advance notification to fishermen, the fishing industry, and the general public that the U.S. longline fishery for bigeye tuna in the Convention Area will be closed during the dates provided in the **DATES** heading. The fishery is scheduled to reopen on January 1, 2017. This rule does not apply to the longline fisheries of American Samoa, Guam, or the Commonwealth of the Northern Mariana Islands, collectively "the territories," as described below.

During the closure, a U.S. fishing vessel may not retain on board, transship, or land bigeye tuna caught by longline gear in the Convention Area, except that any bigeye tuna already on board a fishing vessel upon the effective date of the restrictions may be retained on board, transshipped, and landed, provided that they are landed within 14 days of the start of the closure, that is, by August 5, 2016. This 14-day landing requirement does not apply to a vessel that has declared to NMFS, pursuant to 50 CFR 665.803(a), that the current trip type is shallow-setting.

Longline-caught bigeye tuna may be retained on board, transshipped, and landed if the fish are caught by a vessel with a valid American Samoa longline permit, or landed in the territories. In either case, the following conditions must be met:

(1) The fish is not caught in the U.S. Exclusive Economic Zone (EEZ) around Hawaii;

(2) Other applicable laws and regulations are followed; and

(3) The vessel has a valid permit issued under 50 CFR 660.707 or 665.801.

Bigeye tuna caught by longline gear during the closure may also be retained on board, transshipped, and/or landed if they are caught by a vessel that is included in a specified fishing agreement under 50 CFR 665.819(c), in accordance with 50 CFR 300.224(f)(1)(iv).

During the closure, a U.S. vessel is also prohibited from transshipping bigeye tuna caught in the Convention Area by longline gear to any vessel other than a U.S. fishing vessel with a valid permit issued under 50 CFR 660.707 or 665.801.

The catch limit and this closure do not apply to bigeye tuna caught by longline gear outside the Convention Area, such as in the eastern Pacific

Ocean. To ensure compliance with the restrictions related to bigeye tuna caught by longline gear in the Convention Area, however, the following requirements apply during the closure period (see 50 CFR 300.224):

(1) Longline fishing both inside and outside the Convention Area is not allowed during the same fishing trip. An exception would be a fishing trip that is in progress on July 22, 2016. In that case, the catch of bigeye tuna must be landed by August 5, 2016; and

(2) If a longline vessel fishes outside the Convention Area and the vessel then enters the Convention Area during the same fishing trip, the fishing gear must be stowed and not readily available for fishing in the Convention Area. Specifically, hooks, branch lines, and floats must be stowed and the mainline hauler must be covered.

The above two additional prohibitions do not apply to the following vessels:

(1) Vessels on declared shallow-setting trips pursuant to 50 CFR 665.803(a); and

(2) Vessels operating in the longline fisheries of the territories. This includes vessels included in a specified fishing agreement under 50 CFR 665.819(c), in accordance with 50 CFR 300.224(f)(1)(iv). This group also includes vessels with valid American Samoa longline permits and vessels landing bigeye tuna in one of the territories, as long as the bigeye tuna were not caught in the EEZ around Hawaii, the fishing was compliant with all applicable laws, and the vessel has a valid permit issued under 50 CFR 660.707 or 665.801.

Classification

There is good cause under 5 U.S.C. 553(b)(B) to waive prior notice and the opportunity for public comment on this action, because it would be contrary to the public interest. This rule closes the U.S. longline fishery for bigeye tuna in the western and central Pacific as a result of reaching the applicable bigeye tuna catch limit. The limit is codified in Federal regulations and is based on agreed limits established by the Western and Central Pacific Fisheries Commission. NMFS forecasts that the fishery will reach the 2016 limit by July 22, 2016. Longline fishermen have been subject to longline bigeye tuna limits in the western and central Pacific since 2009. They have received ongoing, updated information about the 2016 catch and progress of the fishery in reaching the Convention Area limit via the NMFS Web site, social media, and other means. This constitutes adequate advance notice of this fishery closure. Additionally, the publication timing of this rule provides longline fishermen with seven days' advance notice of the closure date, and allows two weeks to return to port and land their catch of bigeye tuna.

For the reasons stated above, there is also good cause under 5 U.S.C. 553(d)(3) to waive the 30-day delay in effectiveness for this temporary rule. NMFS must close the fishery as soon as possible to ensure that fishery does not exceed the catch limit. According to NMFS stock-status-determination criteria, bigeye tuna in the Pacific Ocean are currently experiencing overfishing. NMFS implemented the catch limit to reduce the effects of fishing on bigeye tuna and restore the stock to levels capable of producing maximum sustainable yield on a continuing basis. Failure to close the fishery immediately would result in additional fishing pressure on this stock, in violation of Federal law and regulations that implement WCPFC decisions.

This action is required by 50 CFR 300.224 and is exempt from review under Executive Order 12866.

Authority: 16 U.S.C. 6901 *et seq.*

Dated: July 12, 2016.

Emily H. Menashes,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2016–16754 Filed 7–12–16; 4:15 pm]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 81, No. 136
Friday, July 15, 2016

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Parts 1220 and 1260

[No. AMS–LPS–13–0083]

RIN 0581–AD49

Soybean Promotion, Research, and Consumer Information; Beef Promotion and Research; Amendments To Allow Redirection of State Assessments to the National Program; Technical Amendments

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule.

SUMMARY: This proposed rule would amend the Soybean Promotion, Research, and Consumer Information Order (Soybean Order) and the Beef Promotion and Research Order (Beef Order) to add provisions allowing soybean and beef producers to request, under certain circumstances, that their assessments paid to a State board or council authorized under their respective statutes, be redirected to the national program. The proposed rule also would make technical amendments to the Beef Order.

DATES: Written comments must be received by September 13, 2016. Pursuant to the Paperwork Reduction Act, comments on the information collection burden that would result from this proposal must be received by September 13, 2016.

ADDRESSES: Interested persons are invited to submit written comments on the Internet at *www.regulations.gov* or to Kevin Studer; Research and Promotion Division; Livestock, Poultry, and Seed Program; Agricultural Marketing Service, USDA, Room 2608–S, STOP 0249, 1400 Independence Avenue SW., Washington, DC 20250–0249; or fax to (202) 720–1125. All comments should reference the docket number, the date, and the page number of this issue of the **Federal Register** and will be available for public inspection at the above office during regular business hours.

Pursuant to the Paperwork Reduction Act (PRA), send comments regarding the accuracy of the burden estimate, ways to minimize the burden, including the use of automated collection techniques or other forms of information technology, or any other aspect of this collection of information to the above address. Comments concerning the information collection under the PRA should also be sent to the Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

Please be advised that all comments submitted in response to this notice will be included in the record and will be made available to the public on the Internet at *http://www.regulations.gov.* Also, the identity of the individuals or entities submitting the comments will be made public.

FOR FURTHER INFORMATION CONTACT: Kevin Studer, Research and Promotion Division, at (202) 253–2380, fax (202) 720–1125, or by email at *Kevinj.Studer@ams.usda.gov.*

SUPPLEMENTARY INFORMATION:

Executive Order 12866

The Office of Management and Budget (OMB) has waived the review process required by Executive Order 12866 for this action.

Executive Order 12988

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. It is not intended to have retroactive effect.

Executive Order 13175

The Agricultural Marketing Service (AMS) has assessed the impact of this proposed rule on Indian tribes and determined that this rule would not, to our knowledge, have tribal implications that require tribal consultation under Executive Order 13175. If a Tribe requests consultation, AMS will work with the Department of Agriculture's (USDA) Office of Tribal Relations to ensure meaningful consultation is provided where changes, additions, and modifications are identified in this proposed rule.

Soybean Order

The Soybean Promotion, Research, and Consumer Information Act (Soybean Act) (7 U.S.C. 6301–6311) provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 1971 of the Soybean Act, a person subject to the Soybean Order may file a petition with USDA stating that the Soybean Order, any provision of the Soybean Order, or any obligation imposed in connection with the Soybean Order, is not in accordance with the law and request a modification of the Soybean Order or an exemption from the Soybean Order. The petitioner is afforded the opportunity for a hearing on the petition. After a hearing, USDA would rule on the petition. The Soybean Act provides that district courts of the United States in any district in which such person is an inhabitant, or has their principal place of business, has jurisdiction to review USDA's ruling on the petition, if a complaint for this purpose is filed within 20 days after the date of the entry of the ruling.

Further, section 1974 of the Soybean Act provides, with certain exceptions, that nothing in the Soybean Act may be construed to preempt or supersede any other program relating to soybean promotion, research, consumer information, or industry information organized under the laws of the United States or any State. One exception in the Soybean Act concerns assessments collected by Qualified State Soybean Boards (QSSBs). The exception provides that to ensure adequate funding of the operations of QSSBs under the Soybean Act, no State law or regulation may limit or have the effect of limiting the full amount of assessments that a QSSB in that State may collect, and which is authorized to be credited under the Soybean Act. Another exception concerns certain referenda conducted during specified periods by a State relating to the continuation of a QSSB or State soybean assessment.

Beef Order

Section 11 of the Beef Research and Promotion Act of 1985 (Beef Act) (7 U.S.C. 2901–2911) provides that nothing in the Beef Act may be construed to preempt or supersede any other program relating to beef promotion organized and operated under the laws of the United States or any State.

Background and Proposed Action

Soybean Order Amendments

The Soybean Act and the Soybean Order issued thereunder authorize the collection of an assessment from soybean producers of one-half of one percent (0.5 percent) of the net market value of soybeans, processed soybeans, or soybean products. In most cases, these assessments are collected by QSSBs that retain up to half of the assessments as authorized by the Soybean Act. The QSSBs as defined under Section 1967 (14) of the Soybean Act will forward the remainder to the United Soybean Board (Soybean Board), which administers the national soybean checkoff program.[1]

The original Soybean Order, which became effective July 9, 1991, mandated that all producers marketing soybeans pay an assessment of one-half of one percent (0.5 percent) of the net market price of the market price of soybeans sold. The original Soybean Order contained a provision in § 1220.228(b)(5)(i), which required QSSBs that were authorized or required to pay refunds to producers to certify to the Soybean Board that they would honor any request from a producer for a refund from the QSSB by forwarding to the Soybean Board those contributions for which the producer received a credit, pursuant to § 1220.223(a)(3). In other words, this section implicitly authorized refunds by the QSSB if State law allowed or required the QSSB to pay refunds; it further directed that the producer receive a credit for those refunds, with the amount sent to the Soybean Board.

Refunds under the soybean program were discontinued on October 1, 1995, after the Secretary determined through a producer poll that continuation of refunds was not favored by a majority of producers. In late 1995, 7 CFR 1220.228(b)(5)(i) was removed as part of rulemaking to eliminate obsolete regulatory language. However, this action had an unintended effect of inadvertently allowing QSSBs to retain a portion of the assessment even if not required by State law, under any circumstances.

In States where payments to a QSSB are not required by State law, the opportunity for producers to choose to direct the full federal assessment to the Soybean Board is already AMS' current policy; this rule is intended to formalize the policy. Therefore, AMS proposes adding provisions that remedy the removal of the original refund language. A new provision would be added to the Soybean Order to (i) require producers in States where refunds are authorized to forward that refund to the Soybean Board and (ii) provide an opportunity for a refund if the QSSB is not authorized by State statute but is organized and operating within a State and is certified by the Soybean Board, as provided by § 1220.228(a)(2). AMS proposes to require that the form must be postmarked by the 30th day of the month following the month the soybeans were sold. Assessments would not be able to be retroactively redirected from the QSSB to the Soybean Board. Likewise, AMS proposes to require that the QSSB must respond by the last day of the month following the month in which the OMB-approved QSSB–1 form was received.

Regardless of a State's requirements or refunding provisions, a producer is required by the Soybean Act to pay an assessment of one-half of one percent (0.5 percent) of the net market value of soybeans, processed soybeans, or soybean products. Several States have additional producer assessments, mandated by State statutes that are collected in addition to the assessment required by the Soybean Act as set forth in the chart provided. If a QSSB offers a producer refund under a State statute, the QSSB can only refund to the producer any State assessment collected in excess of the assessment that the producer is required to pay under the Soybean Act. AMS proposes that the portion of the assessment compelled by the Soybean Act that the QSSB would normally keep can be redirected to the national program by the producer if State law allows.

Examples

- A soybean producer in California pays an assessment for a soybean sale. The assessment is collected by a certified Western Region Soybean Board, which keeps 50% and forwards the remaining 50% to the Soybean Board. California has no State law requiring a California assessment, so the California producer *may* request that the 50% of the assessment amount retained by the Western Region Soybean Board be redirected to the Soybean Board.
- A soybean producer in Iowa pays an assessment for a soybean sale. The assessment is collected by Iowa Soybean Promotion Board, which keeps 50% and forwards the remaining 50% to the Soybean Board. Iowa has a State law with a refund provision, so the Iowa producer *may* request that the 50% of the assessment amount retained by the Iowa Soybean Promotion Board be redirected to the Soybean Board.
- A soybean producer in Virginia pays an assessment for a soybean sale. The assessment is collected by the Virginia Soybean Board which keeps 50% and forwards the remaining 50% to the Soybean Board. Virginia has a State law with no refund provision, so the Virginia soybean producer *may not* request that the 50% of the assessment amount retained by the Virginia Soybean Board be redirected to the Soybean Board.

Beef Order Amendments

Similarly, the Beef Promotion and Research Act of 1985 (Beef Act) and the Beef Promotion and Research Order (Beef Order) issued thereunder authorize the collection of an assessment from cattle producers of $1.00 per head of cattle sold. In most cases, these assessments are collected by Qualified State Beef Councils (QSBCs) that retain up to one-half of the assessments as authorized by the Beef Act. The QSBCs, as defined under Section 3(14) of the Beef Act, are required to forward the remainder to the Cattlemen's Beef Promotion and Research Board (Beef Board), which administers the national beef checkoff program.[2]

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[1] Section 1967(14) of the Soybean Act states:

(14) QUALIFIED STATE SOYBEAN BOARD. The term "qualified State soybean board" means a State soybean promotion entity that is authorized by State law. If no such entity exists in a State, the term "qualified State soybean board" means a soybean producer-governed entity)—(A) that is organized and operating within a State; (B) that receives voluntary contributions and conducts soybean promotion, research, consumer information, or industry information programs; and (C) that meets criteria established by the Board as approved by the Secretary relating to the qualifications of such entity to perform duties under the order and is recognized by the Board as the soybean promotion and research entity within the State.

Likewise, 7 CFR 1220.122 of the Soybean Order states:

The term *Qualified State Soybean Board* means a State soybean promotion entity that is authorized by State law and elects to be the Qualified State Soybean Board for the State in which it operates pursuant to § 1220.228(a)(1). If no such entity exists in a State, the term *Qualified State Soybean Board* means a soybean producer-governed entity—

(a) That is organized and operating within a State; (b) That receives voluntary contributions and conducts soybean promotion, research, consumer information, or industry information programs; and (c) That meets the criteria, established by the Board and approved by the Secretary, relating to the qualifications of such entity to perform its duties under this part as determined by the Board, and is certified by the Board under § 1220.228(a)(2), with the approval of the Secretary.

[2] Section 3(14) of the Beef Act states that "the term "qualified State beef council" means a beef promotion entity that is authorized by State statute or is organized and operating within a State, that receives voluntary contributions and conducts beef promotion, research, and consumer information programs, and that is recognized by the Board as the beef promotion entity within such State." Likewise, 7 CFR 1260.115 of the Beef Order states "*Qualified*

Continued

The original Beef Order, which became effective July 18, 1986, mandated that all producers owning and marketing cattle pay an assessment of $1.00 per head of cattle, to be collected each time cattle are sold. The original Beef Order contained a provision in § 1260.181(b)(5), which required QSBCs that were authorized or required by State law to pay refunds to producers to certify to the Beef Board that they would honor any request from a producer for a refund from the QSBC by forwarding to the Beef Board those contributions for which the producer received a credit, pursuant to § 1260.172(a)(3). In other words, this section authorized refunds by the QSBC if State law allowed or required the QSBC to pay refunds; it further directed that the producer receive a credit for those refunds, with the amount redirected to the Beef Board.

In a May 10, 1988, referendum conducted by the Secretary, cattle producers and importers voted to institute mandatory assessments. In late 1995, 7 CFR 1260.181(b)(5) was removed as part of rulemaking to eliminate obsolete regulatory language. However, this action had an unintended effect of inadvertently allowing QSBCs to retain a portion of the $1.00-per-head assessment even if not required by State law, under any circumstances. Therefore, AMS proposes adding provisions that would remedy the removal of the original language in § 1260.181(b)(5).

Furthermore, while the Beef Act and Beef Order authorize QSBCs to retain up to 50 cents per head of cattle assessed, neither the Beef Act nor the Beef Order require producers to contribute a portion of the $1.00-per-head assessment to a QSBC. Thus, unless State statutes require the collection of the $1.00-per-head assessment set forth in the Beef Act (the federal assessment) or require producers to contribute a portion of the $1.00-per-head federal assessment to the State beef council, producers may be able to choose not to contribute up to 50 cents per head of the federal assessment to their QSBC. While the original Beef Order did not address the specific situation that allows producers to choose not to contribute up to 50 cents per head of the federal assessment to a QSBC, AMS proposes to address this in the new language. A new provision would be added to the Beef Order to (i) require QSBCs in States where refunds to producers of the $1.00-per-head assessment collected per the Beef Act and Beef Order are authorized by State statute to forward that refund to the Beef Board, and (ii) provide an opportunity for producers to choose to direct the full $1.00-per-head federal assessment to the Beef Board in States where State law does not require the collection of the $1.00-per-head assessment set forth in the Beef Act (the federal assessment) or in States where State statutes do not require producers to contribute a portion of the $1.00-per head federal assessment to the State beef council. In States where payments to a QSBC are not required by State law, the opportunity for producers to choose to direct the full $1.00-per-head federal assessment to the Beef Board is already AMS' current policy; this rule is intended to formalize the policy. As QSBCs are responsible for collecting assessments on cattle sold in or originating in their State (§ 1260.172(a)(5) and § 1260.181(b)(3)), producers who are allowed refunds under State statutes and choose to redirect the full $1.00-per-head assessment to Beef Board must submit to the QSBC a written request on an approved request form. AMS proposes to require that the form must be postmarked by the 15th day of the month following the month the cattle were sold. Assessments would not be able to be retroactively redirected from the QSBC to the Beef Board, and QSBCs would be required to respond to such requests within 60 days.

Regardless of a State's requirements or refunding provisions, a producer is required by the Beef Act to pay an assessment of $1.00 on each head of cattle sold. Several States have additional producer assessments, mandated by State statutes, that are collected in addition to the $1.00-per-head assessment required by the Beef Act. If a QSBC offers a producer refund under a State statute, the QSBC can only refund to the producer any State assessment collected in addition to the $1.00-per-head assessment that the producer is required to pay under the Beef Act. AMS proposes that the portion of the $1.00-per-head federal assessment that the QSBC would normally keep under § 1260.181(b)(4) can be redirected to the national program by the producer if State law allows.

Examples

- A producer in Kansas pays the $1.00 federal assessment for a cattle sale. The Kansas Beef Council collects $1.00, keeps $0.50, and forwards $0.50 to the Beef Board. Since there is no Kansas law compelling producers to contribute to the Kansas Beef Council, the producer *may* request that the $0.50 of the original $1.00 assessment be redirected to the Beef Board.
- A producer in Colorado pays $1.00 in assessments for a cattle sale. The Colorado Beef Council collects $1.00, keeps $0.50, and forwards $0.50 to the Beef Board. Colorado State law requires an assessment but allows a refund. The producer *may* request that the $0.50 cents of the original $1.00 assessment be redirected to the Beef Board.
- A producer in California pays $1.00 in assessments for a cattle sale. The California Beef Council collects $1.00, keeps $0.50, and forwards $0.50 to the Beef Board. California law compels the collection of the $1.00-per-head assessment and does not provide for a refund. The producer *may not* request the California Beef Council to redirect any portion of the $0.50 to the Beef Board.
- A producer in Idaho pays the $1.00-per-head federal assessment plus the $0.50-per-head State-mandated assessment for a cattle sale. The Idaho Beef Council collects $1.50, keeps $1.00, and forwards $0.50 to the Beef Board. The producer requests a refund of all funds paid to the Idaho Beef Council. The Idaho Beef Council may refund the $0.50-per-head State assessment to the producer, but the producer is required to pay $1.00 under the Beef Act. Since Idaho State law only compels an assessment of $0.50, which is refundable, the producer *may* request the Idaho Beef Council to redirect the remaining $0.50 of the $1.00 retained from the original $1.00-per-head federal assessment to the Beef Board.

Regulatory Flexibility Act

Pursuant to the requirements set forth in the Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612), the Administrator of the AMS has considered the economic effect of this action on small entities and has determined that this proposed rule will not have a significant economic impact on a substantial number of small entities. The purpose of RFA is to fit regulatory actions to the scale of businesses subject to such actions in order that small businesses will not be unduly burdened.

Soybean Industry

USDA's Farm Service Agency estimates that there are 569,998 soybean producers subject to the Soybean Order. This estimate comes from including all soybean producers engaged in the production of soybeans in the previous 2 years. The majority of producers subject to the Soybean Order are small

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State beef council means a beef promotion entity that is authorized by State statute or a beef promotion entity organized and operating within a State that receives voluntary assessments or contributions; conducts beef promotion, research, and consumer and industry information programs; and that is certified by the Board pursuant to this subpart as the beef promotion entity in such State."

businesses under the criteria established by the Small Business Administration (SBA) [13 CFR 121.201]. SBA defines small agricultural producers as those having annual receipts of less than $750,000.

This proposed rule imposes no new burden on the soybean industry. It would provide soybean producers, under certain circumstances, the option of requesting that their assessments paid to a State board be directed to the national program.

However, the proposed rule could result in decreased assessment funds for some QSSBs, depending on whether a State statute is in place, whether refund provisions are included, and whether the producer chooses to exercise the refund provision.

POTENTIAL FINANCIAL IMPACT ON QSSBS BY STATE

[Current as of 05/01/2016]

State[1]	State law requirement	Refund option	Amount of national assessment retained by state (50% of assessments due under Soybean Act)[2] (FY 2015)
Alabama	Statute establishes $0.02 per bushel maximum assessment; regulations establish $0.01 per bushel maximum assessment.	Yes	$445,917
Arizona[4]	5% of the annual gross sales dollar value maximum annual assessment.	No	
Arkansas	$0.02 per bushel; 0.25% of net market price during continuance of federal program.	Yes, on both	3,946,583
California[4]	None	Not applicable	
Colorado[4]	None	Not applicable	
Connecticut[3]	None	Not applicable	
Delaware	None beyond federal	Yes (under general promotion statute).	245,921
Georgia	0.05 per bushel	No	195,398
Idaho[4]	None	Not applicable	
Illinois	Statute establishes ½ of 1% of the net market price of soybeans produced and sold.	Yes	13,941,988
Indiana	None beyond federal	Yes	7,855,049
Iowa	If national assessment collection, 0.25% of net market price; if not, 0.5% of net market price.	Yes	12,788,353
Kansas	Statute sets maximum at 0.5% of net market price while federal program effective; regulation sets assessment at 20 mills ($0.02) per bushel as State default assessment.	Yes, provided refund amount is $5 or more.	3,415,025
Kentucky	0.25% of net market price per bushel on all soybeans marketed within Kentucky.	Yes	2,148,849
Louisiana	0.01 per bushel on all soybeans grown in Louisiana	Yes	2,131,537
Maine[3]	None beyond federal	No	
Maryland	None beyond federal	Yes	588,195
Massachusetts[3]	None	Not applicable	
Michigan	None beyond federal	Yes, for funds left over at close of marketing season.	2,329,254
Minnesota	General statute sets maximum at 1% of the market value of the year's production of participating producers; MN Soybean and Research and Promotion Council sets assessment at 0.5%.	Yes	8,151,802
Mississippi	0.01 per bushel	Yes	2,955,549
Missouri	None beyond federal	Yes	6,419,003
Montana[4]	None beyond federal	No	
Nebraska	None beyond federal	No	6,952,254
Nevada[4]	None	Not applicable	
New Hampshire[3]	None	Not applicable	
New Jersey	None beyond federal	No	110,113
New Mexico[4]	None beyond federal	No	
New York	None beyond federal	Yes, but left to discretion of commissioner.	254,297
North Carolina	None beyond federal	Yes, if assessment enacted	1,768,352
North Dakota	0.5% of sale value	No	4,913,972
Ohio	None beyond federal; capped at 2 cents per bushel if assessment enacted.	Yes	6,575,663
Oklahoma	None beyond federal	Yes	279,962
Oregon[4]	None beyond federal	No	
Pennsylvania	None beyond federal	No	618,190
Rhode Island[3]	None	Not applicable	
South Carolina	0.005 per bushel	Yes	367,307
South Dakota	0.5% of value of the net market price	Yes	5,185,112
Tennessee	0.01 per bushel	Yes	1,985,565
Texas	None beyond federal	Yes	117,588
Utah[4]	None beyond federal	No	

POTENTIAL FINANCIAL IMPACT ON QSSBs BY STATE—Continued

[Current as of 05/01/2016]

State[1]	State law requirement	Refund option	Amount of national assessment retained by state (50% of assessments due under Soybean Act)[2] (FY 2015)
Vermont[3]	None beyond federal	No	
Virginia	Statute allows $0.02 per bushel; regulation specifies $0.01 per bushel.	No	645,754
Washington[4]	None beyond federal	No	
West Virginia[3]	None	Not applicable	
Wisconsin	Capped by statute at $0.02 per bushel; actual assessment determined annual by board.	Yes	1,838,960
Wyoming[4]	None beyond federal	No	
Eastern Region[5]			48,391
Western Region[6]			17,121

[1] There are 31 QSSBs. Two represent multiple States.

[2] Only includes 50 percent of the national assessment that the State retains; does not include State assessment revenue derived from an independent State assessment. In addition, the notation—indicates that the amount of national assessment retained by the state is a de minimis amount.

[3] Covered by Eastern Region.

[4] Covered by Western Region.

[5] Eastern Region includes Connecticut, Florida, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont, and West Virginia.

[6] "Western Region includes Arizona, California, Colorado, Idaho, Montana, Nevada, New Mexico, Oregon, Utah, Washington, and Wyoming.

The information collection requirements on QSSBs are minimal. QSSBs are already required to remit assessments to the national programs. We have not identified any relevant Federal rules that duplicate, overlap, or conflict with this rule.

Accordingly, the Administrator of AMS has conducted this Initial Regulatory Flexibility Analysis and has determined that this proposed rule will not have a significant economic impact on a substantial number of small soybean entities. However, we invite comments concerning potential effects of this proposed rule.

Beef Industry

In the February 2013, publication of "Farms, Land in Farms, and Livestock Operations," USDA's National Agricultural Statistics Service (NASS) estimates that the number of operations in the United States with cattle in 2012 totaled approximately 915,000, down from 950,000 in 2009. The majority of these operations that are subject to the Beef Order may be classified as small entities. According to the NASS Web site "Farms, Land in Farms, and Livestock Operations," the issues released between 2005 and 2013 included "Livestock Operations" in the title. Beginning in 2014, livestock operations data will be available in the Census of Agriculture and most recent data can be referenced from Census data. This proposed rule imposes no new burden on the beef industry. It would provide beef producers, under certain circumstances, the option of requesting that their assessments paid to a State council be directed to the national program.

However, the proposed rule could result in decreased assessment funds for some QSBCs, depending on whether a State statute is in place, whether refund provisions are included, and whether the producer chooses to exercise the refund provision. Currently, a number of States are in various stages of establishing or amending State laws regarding beef checkoff requirements, so this information is likely to change.

POTENTIAL FINANCIAL IMPACT ON QSBCs BY STATE

[Current as of 05/06/2016]

State[1]	State law requirement[2]	State refund option?	Amount of national assessment retained by state (50% of assessments due under Beef Act)[3] (FY 2015)
Alabama	$1.00 per head beyond federal	Yes	$308,618
Arizona	None beyond federal	No	326,251
Arkansas	None beyond federal	Yes	366,702
California	None beyond federal	No	1,810,135
Colorado	None beyond federal	Yes	1,364,278
Delaware	None beyond federal	No	4,325
Florida	None beyond federal	Yes	3,340,762
Georgia	1.00 beyond federal	No	270,011
Hawaii	None	Not applicable	15,623
Idaho	0.50 per head beyond federal	Yes	830,548

POTENTIAL FINANCIAL IMPACT ON QSBCS BY STATE—Continued
[Current as of 05/06/2016]

State[1]	State law requirement[2]	State refund option?	Amount of national assessment retained by state (50% of assessments due under Beef Act)[3] (FY 2015)
Illinois	None beyond federal	Yes	296,718
Indiana	None beyond federal	No	215,364
Iowa	None beyond federal	If State assessment collected, refund available	1,636,842
Kansas	None	Not applicable	3,385,185
Kentucky	None beyond federal	Yes	624,147
Louisiana	0.50 per head beyond federal	Yes	189,751
Maine	None beyond federal	No	1,914
Maryland	None beyond federal	Yes	43,891
Michigan	None beyond federal	No	284,914
Minnesota	None beyond federal	Yes	685,484
Mississippi	None beyond federal	Yes	222,968
Missouri	None beyond federal	No	1,160,733
Montana	None beyond federal	Yes	866,981
Nebraska	None beyond federal	No	3,468,679
Nevada	None	Not applicable	112,784
New Jersey	None beyond federal	No	4,771
New Mexico	None beyond federal	Yes	491,527
New York	None beyond federal	No	326,982
North Carolina	None beyond federal	No	162,782
North Dakota	None beyond federal	Yes, when ND Attorney General certifies federal law does not preclude.	534,462
Ohio	1.00 beyond federal	Yes	308,689
Oklahoma	None beyond federal	Yes	1,548,338
Oregon	0.50 beyond federal	Yes, for "incorrect" assessments	427,685
Pennsylvania	None beyond federal	No	372,275
South Carolina	None beyond federal	Yes, at discretion of Commission	79,772
South Dakota	None	Not applicable	1,422,366
Tennessee	0.50 beyond federal	Yes	405,046
Texas	1.00 beyond federal, effective 10/1/14	Yes	4,620,761
Utah	0.50 beyond federal	Yes	264,339
Vermont	None beyond federal	No	50,235
Virginia	None beyond federal	No	366,879
Washington	0.50 beyond federal	No	513,601
Wisconsin	None beyond federal	No	696,796
Wyoming	None beyond federal	No	428,350

[1] There are seven States without a QSBC. They are Alaska, Connecticut, Massachusetts, Maine, New Hampshire, Rhode Island, and West Virginia. In these seven States, the Beef Board collects assessments directly.

[2] Per head of cattle sold.

[3] Only includes 50 percent of the national assessment that the State retains; does not include State assessment revenue derived from an independent State assessment.

The information collection requirements on QSBCs are minimal. QSBCs are already required to remit assessments to the national programs. We have not identified any relevant Federal rules that duplicate, overlap, or conflict with this rule.

Accordingly, the Administrator of AMS has conducted this Initial Regulatory Flexibility Analysis and has determined that this proposed rule will not have a significant economic impact on a substantial number of small cattle or beef entities. However, we invite comments concerning potential effects of this proposed rule.

Paperwork Reduction Act

The information collection and recordkeeping requirements that are imposed by the Soybean and Beef Orders have been approved previously under OMB control number 0581–0093. In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), this proposed rule also announces that AMS is seeking emergency approval for a new information collection request allowing soybean and beef producers, under certain circumstances, to request that assessments paid to a QSSB or QSBC be redirected to the Soybean Board or Beef Board, respectively. The additional burden is optional and is only imposed if a producer wants to divert assessments to the national program. According to the Beef Board, there have been very few requests from producers seeking redirection of assessments to the Beef Board. Additionally, the Soybean Board has not reported any requests from producers seeking redirection of assessments to the Soybean Board. Therefore, we estimate that annually a small number of soybean producers and beef producers might submit such a request and estimate that it would take an average of 5 minutes per person, resulting in an additional burden of 0.83 hour for the soybean program and 1.67 hours for the beef program.

AMS is committed to complying with the E-Government Act, to promote the use of the Internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes. As with all Federal promotion programs, reports and forms are periodically reviewed to reduce information requirements and duplication by industry and public sector agencies.

Title: Redirection of State Soybean and Beef Assessments to the National Program.

OMB Number: 0581–NEW.

Type of Request: New collection.

Abstract: The information collection requirements are essential to carry out this rule.

The Soybean Act and Order and the Beef Act and Order authorize the collection of assessments from soybean and beef producers. In most cases, these assessments are collected by QSSBs or QSBCs that retain up to half of the assessments. The QSSBs and QSBCs forward the remainder to the Soybean Board and Beef Board, which administer the national soybean and beef checkoff programs.

The original Soybean and Beef Orders contained provisions directing QSSBs and QSBCs, if authorized or required by State law to pay refunds to producers, to honor producer refund requests by forwarding to the national Board that portion of such refunds equal to the amount of credit received by the producer for contributions to the State entities. Amendments to the Soybean and Beef Orders in 1995 to remove obsolete language concerning refunds had an unintended consequence, inadvertently allowing QSSBs and QSBCs to retain a portion of the assessment even if not required by State law, under certain circumstances. Therefore, we propose adding provisions that would remedy the removal of the original language. New provisions would be added to both Orders to (i) require QSSBs and QSBCs in States where refunds to producers are authorized by State statutes to forward such requested refunds to the national board and (ii) provide an opportunity for producers, in States where the State entity is not authorized by State statute or State statutes allow, to choose to direct the full federal assessment to the national Board.

An estimated 10 soybean respondents and 20 beef respondents will provide information to a QSSB or QSBC to request redirection of assessments. The estimated cost of providing the information to the QSSB or QSBC by respondents would be $82.17. This total has been estimated by multiplying 2.49 total hours required for reporting by $33.00, the average mean hourly earnings of various occupations involved in keeping this information. Data for computation of this hourly rate was obtained from the U.S. Department of Labor Statistics.

In turn, QSSBs or QSBCs will respond to those producers with the decision and will forward the assessments and records to the Soybean Board or Beef Board. The estimated cost of the QSSB or QSBC providing the information to producers and the Soybean Board or Beef Board would be $82.17. This total has been estimated by multiplying 2.49 total hours required for reporting by $33.00, the average mean hourly earnings of various occupations involved in keeping this information. Data for computation of this hourly rate was obtained from the U.S. Department of Labor Statistics.

The design of the forms has been carefully reviewed, and every effort has been made to minimize any unnecessary recordkeeping costs or requirements, including efforts to utilize information already submitted under other soybean and beef programs administered by the USDA and other State programs. In fact, the forms to be used by the QSSBs and QSBCs were designed to serve a dual purpose, both for informing producers of the outcome of their requests and for forwarding assessments and information to the Soybean Board and Beef Board. AMS has determined that there is no practical method for collecting the required information without the use of these forms. The forms would be available from the national boards, QSSBs, and QSBCs. The information collection would be used only by authorized QSSB, QSBC, Soybean Board, and Beef Board employees and representatives of USDA, including AMS staff. Authorized QSSB, QSBC, Soybean Board, and Beef Board employees will be the primary users of the information, and AMS will be the secondary user.

The forms require the minimum information necessary to effectively carry out producers' wishes to redirect to the national boards the portion of the assessments that the State entities would otherwise retain. Such information can be supplied without data processing equipment or outside technical expertise. In addition, there are no additional training requirements for individuals filling out the forms and remitting assessments to the QSSBs and QSBCs. The forms will be simple, easy to understand, and place as small a burden as possible on the person filing the form. The forms are entirely voluntary for producers, and QSSBs and QSBCs will only complete their forms as a result of producers' requests.

The form may be submitted at any time, though within the prescribed deadlines, so as to meet the needs of the industry while minimizing the amount of work necessary to complete the forms. In addition, the information to be included on these forms is not available from other sources because such information relates specifically to individual producers who are subject to the provisions of the Soybean or Beef Acts and because there is a need to ensure that producers are paying the full assessment required by law.

Therefore, there is no practical method for collecting the information without the use of these forms.

The request for approval of the new information collection is as follows:

(1) Form QSSB–1, Notification to Qualified State Soybean Board of intent to redirect assessments to the United Soybean Board.

Estimate of Burden: Public reporting burden for this collection of information is estimated to average 5 minutes per soybean producer.

Respondents: Soybean producers in certain States.

Estimated Number of Respondents: 10.

Estimated Number of Responses per Respondent per Year: 1.

Estimated Total Annual Burden on Respondents: 0.83 hours.

(2) Form QSBC–1, Notification to Qualified State Beef Council of intent to redirect assessments to the Cattlemen's Beef Promotion and Research Board.

Estimate of Burden: Public reporting burden for this collection of information is estimated to average 5 minutes per cattle producer.

Respondents: Beef producers in certain States.

Estimated Number of Respondents: 20.

Estimated Number of Responses per Respondent per Year: 1.

Estimated Total Annual Burden on Respondents: 1.66 hours.

Comments: Comments are invited on: (1) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques of other forms of information technology.

A 60-day period is provided to comment on the information collection burden. Comments should reference OMB No. 0581–NEW and be sent to Kevin Studer; Research and Promotion Division; Livestock, Poultry, and Seed Program; Agricultural Marketing Service, USDA, Room 2608–S, STOP 0249, 1400 Independence Avenue SW., Washington, DC 20250–0249; or fax to (202) 720–1125. All comments received will be available for public inspection. All responses to this proposed rule will be summarized and included in the request for OMB approval. All comments will become a matter of public record.

Comments concerning the information collection under the PRA should also be sent to the Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

Beef Technical Amendments

In addition, several technical amendments are proposed to update information in the Beef Promotion and Research Order and rules and regulations:

Section 1260.181 (b)(4) currently requires QSBCs to remit assessments to the Beef Board by the last day of the month in which the QSBC received the assessment "unless the Board determines a different date." The Beef Board's practice has been to require QSBCs to remit assessments by the 15th of the following month. This section would be updated to reflect actual practice.

Section 1260.315 would be amended to reflect the current QSBCs.

List of Subjects

7 CFR Part 1220

Administrative practice and procedure, Advertising, Agricultural research, Marketing agreements, Reporting and recordkeeping requirements, Soybeans and soybean products.

7 CFR Part 1260

Administrative practice and procedure, Advertising, Agricultural research, Imports, Marketing agreement, Meat and meat products, Reporting and recordkeeping requirements.

For reasons set forth in the preamble, it is proposed that 7 CFR parts 1220 and 1260 be amended as follows:

PART 1220—SOYBEAN PROMOTION, RESEARCH, AND CONSUMER INFORMATION

■ 1. The authority citation for part 1220 continues to read as follows:

Authority: 7 U.S.C. 6301–6311 and 7 U.S.C. 7401.

■ 2. In § 1220.228, add a new paragraph (b)(5) to read as follows:

§ 1220.228 Qualified State Soybean Boards.

* * * * *

(b) * * *

* * * * *

(5) If the entity is authorized or required to pay refunds to producers, certify to the Board that any requests from producers for such refunds for contributions to it by the producer will be honored by forwarding to the Board that portion of such refunds equal to the amount of credit received by the producer for contributions pursuant to § 1220.223(a)(3). Entities not authorized by State statute but organized and operating within a State and certified by the Board pursuant to paragraph (a)(2) of this section must provide producers an opportunity for a State refund and must forward that refunded portion to the Board. Producers receiving a refund from a State entity are required to remit that refunded portion to the Board in the manner and form required by the Secretary.

* * * * *

PART 1260—BEEF PROMOTION AND RESEARCH

■ 3. The authority citation for 7 CFR part 1260 continues to read as follows:

Authority: 7 U.S.C. 2901–2911 and 7 U.S.C. 7401.

■ 4. In § 1260.181, revise paragraph (b)(4) and add paragraph (b)(5) to read as follows:

§ 1260.181 Qualified State Beef Councils.

* * * * *

(b) * * *

* * * * *

(4) Certify to the Board that such organization shall remit to the Board assessments paid and remitted to the council, minus authorized credits issued to producers pursuant to § 1260.172(a)(3), by the 15th day of the month following the month in which the assessment was remitted to the qualified State beef council unless the Board determines a different date for remittance of assessments.

(5) Redirection of assessments. Qualified State beef councils which are authorized or required by State statutes to pay refunds to producers must certify to the Board that any requests from producers for refunds from the council for contributions to such council by the producer will be honored by redirecting to the Board that portion of such refunds equal to the amount of credit received by the qualified State beef councils. In States where State law does not require the collection of the $1.00-per-head assessment set forth in the Act (the federal assessment) or in States where State statutes do not require producers to contribute a portion of the $1.00-per head federal assessment to the State beef council, qualified State beef councils must provide an opportunity for producers to choose to direct the full $1.00-per-head federal assessment to the Board. The request to redirect funds to the Board must be submitted on the appropriate form and postmarked by the 15th day of the month following the month the cattle were sold. Requests may not be retroactive. Requests to redirect funds must be submitted by the producer who paid the assessment.

* * * * *

■ 5. In § 1260.312, paragraph (c) is revised to read as follows:

§ 1260.312 Remittance to the Cattlemen's Board or Qualified State Beef Council.

* * * * *

(c) *Remittances.* The remitting person shall remit all assessments to the qualified State beef council or its designee, or, if there is no qualified State beef council, to the Cattlemen's Board at an address designated by the Board, with the report required in paragraph (a) of this section not later than the 15th day of the following month. All remittances sent to a qualified State beef council or the Cattlemen's Board by the remitting persons shall be by check or money order payable to the order of the qualified State beef council or the Cattlemen's Board. All remittances shall be received subject to collection and payment at par.

■ 6. Revise § 1260.315 to read as follows:

§ 1260.315 Qualified State Beef Councils.

The following State beef promotion entities have been certified by the Board as qualified State beef councils:

Alabama Cattlemen's Association
Arizona Beef Council
Arkansas Beef Council
California Beef Council
Colorado Beef Council
Delaware Beef Advisory Board
Florida Beef Council, Inc.
Georgia Beef Board, Inc.
Hawaii Beef Industry Council
Idaho Beef Council
Illinois Beef Council
Indiana Beef Council
Iowa Beef Cattle Producers Association
Kansas Beef Council
Kentucky Beef Cattle Association
Louisiana Beef Industry Council
Maryland Beef Industry Council

Michigan Beef Industry Commission
Minnesota Beef Council
Mississippi Beef Council, Inc.
Missouri Beef Industry Council, Inc.
Montana Beef Council
Nebraska Beef Council
New Jersey Beef Industry Council
Nevada Beef Council
New Mexico Beef Council
New York Beef Industry Council
North Carolina Cattlemen's Association
North Dakota Beef Commission
Ohio Beef Council
Oklahoma Beef Council
Oregon Beef Council
Pennsylvania Beef Council, Inc.
South Carolina Beef Council
South Dakota Beef Industry Council
Tennessee Beef Industry Council
Texas Beef Council
Utah Beef Council
Vermont Beef Industry Council
Virginia Beef Industry Council
Washington State Beef Commission
Wisconsin Beef Council, Inc.
Wyoming Beef Council

Dated: July 11, 2016.

Elanor Starmer,

Administrator, Agricultural Marketing Service.

[FR Doc. 2016–16698 Filed 7–14–16; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2016–7427; Directorate Identifier 2016–NM–041–AD]

RIN 2120–AA64

Airworthiness Directives; Bombardier, Inc. Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to supersede Airworthiness Directive (AD) 2013–02–08, for all Bombardier, Inc. Model CL–600–2B19 (Regional Jet Series 100 & 440) airplanes. AD 2013–02–08 currently requires inspecting the trunnions and upper and lower pins of the horizontal stabilizer trim actuator (HSTA), and replacement or re-identification if necessary; and revising the maintenance program to include safe life limits and inspection requirements for the HSTA. Since we issued AD 2013–02–08, we determined that not all affected attachment pins and trunnions were included in the required inspections. In addition, for certain airplanes on which the replacement in AD 2013–02–08 was done, incorrect attachment hardware may have been used. This proposed AD would require measuring the diameter of certain bolts and attach holes, and, as applicable, measuring the diameter of the attach holes in the trunnions and pins, doing detailed visual inspections of the trunnions, pins, and spacers, doing corrective actions, and re-identifying trunnions and pins. This proposed AD also requires revising the maintenance or inspection program. This proposed AD also removes certain airplanes from the applicability. We are proposing this AD to prevent failure of the attachment pins and trunnions of the HSTA. This condition could result in separation of the horizontal stabilizer, and consequent loss of control of the airplane.

DATES: We must receive comments on this proposed AD by August 29, 2016.

ADDRESSES: You may send comments by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.
- *Hand Delivery:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this NPRM, contact Bombardier, Inc., 400 Côte-Vertu Road West, Dorval, Québec H4S 1Y9, Canada; telephone 514–855–5000; fax 514–855–7401; email *thd.crj@aero.bombardier.com;* Internet *http://www.bombardier.com.* You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–7427; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Cesar Gomez, Aerospace Engineer, Airframe and Mechanical Systems Branch, ANE–171, FAA, New York Aircraft Certification Office, 1600 Stewart Avenue, Suite 410, Westbury, New York 11590; telephone (516) 228–7318; fax (516) 794–5531.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include "Docket No. FAA–2016–7427; Directorate Identifier 2016–NM–041–AD" at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD based on those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

Discussion

On, January 16, 2013, we issued AD 2013–02–08, Amendment 39–17329 (78 FR 7647, February 4, 2013) ("AD 2013–02–08"). AD 2013–02–08 requires actions intended to address an unsafe condition on all Bombardier, Inc. Model CL–600–2B19 (Regional Jet Series 100 & 440) airplanes.

Since we issued AD 2013–02–08, we have determined that not all affected attachment pins and trunnions were included in the required inspections of AD 2013–02–08. In addition, for airplanes on which certain service information was incorporated, incorrect attachment hardware may have been used to re-install the HSTA attachment pins and trunnions.

Transport Canada Civil Aviation (TCCA), which is the aviation authority for Canada, has issued Canadian Airworthiness Directive CF–2016–08, dated March 30, 2016 (referred to after this as the Mandatory Continuing Airworthiness Information, or "the MCAI"), to correct an unsafe condition for certain Bombardier, Inc. Model CL–600–2B19 (Regional Jet Series 100 & 440) airplanes. The MCAI states:

> After the issuance of [Canadian] AD CF–2011–45, it was discovered that the [Canadian] AD did not address all affected Horizontal Stabilizer Tim Actuator (HSTA) attachment pins and trunnions. In addition, it is possible that aeroplanes having incorporated the Initial issue or Revision A, of Bombardier Service Bulletin (SB) 601R–27–160 used incorrect attachment hardware to re-install the HSTA attachment pins or trunnions.
>
> This [Canadian] AD mandates the inspection and rectification, as required, and the re-identification, as required, of the HSTA pins and trunnions and incorporation of a revised Airworthiness Limitation task.

The required actions include measuring the diameter of the bolts that attach the trunnions and pins, measuring the diameter of the attach holes in the aircraft structure, and, as applicable, measuring the diameter of the attach holes in the trunnions and pins, doing detailed visual inspections for gouges, scratches, and corrosion of the trunnions and pins, doing detailed visual inspections for damage of the spacers, doing corrective actions, and re-identifying trunnions and pins. Corrective actions include replacing bolts, trunnions, pins, and spacers, increasing the diameter of the attach holes, and repairing trunnions and pins.

This proposed AD also removes certain airplanes from the applicability to correspond with the MCAI, which removed them from its applicability.

You may examine the MCAI in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–7427.

Related Service Information Under 1 CFR Part 51

Bombardier has issued Service Bulletin 601R–27–160, Revision D, dated October 22, 2015. The service information describes procedures for measuring the diameter of certain bolts and attach holes, and, as applicable, measuring the diameter of the attach holes in the trunnions and pins, doing detailed visual inspections of the trunnions, pins, and spacers, doing corrective actions, and re-identifying trunnions and pins.

Bombardier has also issued Bombardier Temporary Revision 2B–2245, dated October 17, 2014, to Appendix B—Airworthiness Limitations, of Part 2, Airworthiness Requirements, of the Bombardier CL–600–2B19 Maintenance Requirements Manual to incorporate a revised Airworthiness Limitation task. The service information describes safe life limits for the HSTA trunnion support and attaching hardware.

Bombardier has also issued Bombardier Temporary Revision 2B–2186, dated August 8, 2011, to Appendix B—Airworthiness Limitations, Part 2, Airworthiness Requirements, of the Bombardier CL–600–2B19 Maintenance Requirements Manual to incorporate a revised Airworthiness Limitation task. The service information describes an inspection of the upper and lower installation pins of the horizontal stabilizer pitch trim actuator.

This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

FAA's Determination and Requirements of This Proposed AD

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to our bilateral agreement with the State of Design Authority, we have been notified of the unsafe condition described in the MCAI and service information referenced above. We are proposing this AD because we evaluated all pertinent information and determined an unsafe condition exists and is likely to exist or develop on other products of the same type design.

Costs of Compliance

We estimate that this proposed AD affects 489 airplanes of U.S. registry.

We estimate that it would take about 8 work-hours per product to comply with the basic requirements of this proposed AD. The average labor rate is $85 per work-hour. Based on these figures, we estimate the cost of this proposed AD on U.S. operators to be $332,520, or $680 per product.

In addition, we estimate that any necessary follow-on actions would take about 20 work-hours and require parts costing $4,391, for a cost of $6,091 per product. We have no way of determining the number of products that may need these actions.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. "Subtitle VII: Aviation Programs," describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in "Subtitle VII, Part A, Subpart III, Section 44701: General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this proposed regulation:

1. Is not a "significant regulatory action" under Executive Order 12866;
2. Is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);
3. Will not affect intrastate aviation in Alaska; and
4. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by removing Airworthiness Directive AD 2013–02–08, Amendment 39–17329 (78 FR 7647, February 4, 2013), and adding the following new AD:

Bombardier, Inc.: Docket No. FAA–2016–7427; Directorate Identifier 2016–NM–041–AD.

(a) Comments Due Date

We must receive comments by August 29, 2016.

(b) Affected ADs

This AD replaces AD 2013–02–08, Amendment 39–17329 (78 FR 7647, February 4, 2013) ("AD 2013–02–08").

(c) Applicability

This AD applies to Bombardier, Inc. Model CL–600–2B19 (Regional Jet Series 100 & 440) airplanes, certificated in any category, serial numbers 7003 through 8113 inclusive.

(d) Subject

Air Transport Association (ATA) of America Code 27: Flight controls.

(e) Reason

This AD was prompted by a determination that not all affected attachment pins and trunnions were included in the inspections required by AD 2013–02–08. In addition, for certain airplanes on which the replacement in AD 2013–02–08 was done, incorrect attachment hardware may have been used. We are issuing this AD to prevent failure of the attachment pins and trunnions of the horizontal stabilizer trim actuator (HSTA). This condition could result in separation of the horizontal stabilizer, and consequent loss of control of the airplane.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Inspection

(1) For airplanes on which the detailed inspection specified in Bombardier Service Bulletin 601R–27–160, dated September 29, 2011; or Bombardier Service Bulletin 601R–27–160, Revision A, dated October 3, 2012, has not been done as of the effective date of this AD: At the earliest of the times specified in paragraphs (g)(1)(i), (g)(1)(ii), and (g)(1)(iii) of this AD, measure the diameter of the bolts that attach the trunnions and pins, measure the diameter of the attach holes in the aircraft structure, and, as applicable, measure the diameter of the attach holes in the trunnions and pins, do detailed visual inspections for gouges, scratches, and corrosion of the trunnions and pins, do detailed visual inspections for damage of the spacers, do corrective actions, and re-identify trunnions and pins, in accordance with Part A of the Accomplishment Instructions of Bombardier Service Bulletin 601R–27–160, Revision D, dated October 22, 2015; except as required by paragraph (h) of this AD. Do all applicable corrective actions before further flight.

(i) Within 5,000 flight hours after March 11, 2013 (the effective date of AD 2013–02–08).

(ii) Within 60 months after March 11, 2013 (the effective date of AD 2013–02–08).

(iii) Before the accumulation of 40,000 total flight cycles, or within 60 days after March 11, 2013 (the effective date of AD 2013–02–08), whichever occurs later.

(2) For airplanes on which the detailed inspection specified in Bombardier Service Bulletin 601R–27–160, dated September 29, 2011; or Bombardier Service Bulletin 601R–27–160, Revision A, dated October 3, 2012, has been done as of the effective date of this AD: Within 9,600 flight hours or 60 months after the effective date of this AD, whichever occurs first; measure the diameter of the bolts that attach the trunnions and pins, measure the diameter of the attach holes in the aircraft structure, and, as applicable, measure the diameter of the attach holes in the trunnions and pins, do detailed visual inspections for gouges, scratches, and corrosion of the trunnions and pins, do detailed visual inspections for damage of the spacers, do corrective actions, and re-identify trunnions and pins, in accordance with Part B of the Accomplishment Instructions of Bombardier Service Bulletin 601R–27–160, Revision D, dated October 22, 2015, except as required by paragraph (h) of this AD. Do all applicable corrective actions before further flight.

(h) Exception to Service Information

Where Bombardier Service Bulletin 601R–27–160, Revision D, dated October 22, 2015, specifies to contact Bombardier for disposition, before further flight, repair using a method approved by the Manager, New York Aircraft Certification Office (ACO), ANE–170, FAA; or Transport Canada Civil Aviation (TCCA); or Bombardier, Inc.'s TCCA Design Approval Organization (DAO).

(i) Credit for Previous Actions

This paragraph provides credit for the actions specified in paragraph (g) of this AD, if those actions were performed before the effective date of this AD using the service information identified in paragraphs (i)(1) and (i)(2) of this AD, which are not incorporated by reference in this AD.

(1) Bombardier Service Bulletin 601R–27–160, Revision B, dated February 20, 2015.

(2) Bombardier Service Bulletin 601R–27–160, Revision C, dated May 3, 2015.

(j) Revision of Maintenance or Inspection Program

(1) Within 30 days after March 11, 2013 (the effective date of AD 2013–02–08), revise the maintenance or inspection program, as applicable, to incorporate the information specified in Bombardier Temporary Revision 2B–2186, dated August 8, 2011, to Appendix B—Airworthiness Limitations, Part 2, Airworthiness Requirements, of the Bombardier CL–600–2B19 Maintenance Requirements Manual. The compliance time for doing the initial inspection of the upper and lower installation pins of the horizontal stabilizer pitch trim actuator is before the accumulation of 40,000 landings or within 60 days after March 11, 2013, whichever occurs later.

(2) Within 30 days after the effective date of this AD, revise the maintenance or inspection program, as applicable, to incorporate the information specified in Bombardier Temporary Revision 2B–2245, dated October 17, 2014; to Appendix B—Airworthiness Limitations, Part 2, Airworthiness Requirements, of the Bombardier CL–600–2B19 Maintenance Requirements Manual. The compliance time for doing the initial replacement for the HSTA trunnion support and attaching hardware is before the accumulation of 80,000 landings or within 60 days after the effective date of this AD, whichever occurs later.

(k) No Alternative Actions or Intervals

After accomplishing the revision required by paragraph (j) of this AD, no alternative actions (*e.g.*, inspections) or intervals may be used unless the actions or intervals are approved as an alternative method of compliance (AMOC) in accordance with the procedures specified in paragraph (l)(1) of this AD.

(l) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, New York ACO, ANE–170, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the ACO, send it to ATTN: Program Manager, Continuing Operational Safety, FAA, New York ACO, 1600 Stewart Avenue, Suite 410, Westbury, New York 11590; telephone 516–228–7300; fax 516–794–5531. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office. The AMOC approval letter must specifically reference this AD.

(2) *Contacting the Manufacturer:* As of the effective date of this AD, for any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, New York ACO, ANE–170, Engine and Propeller Directorate, FAA; or TCCA; or Bombardier, Inc.'s TCCA DAO. If approved by the DAO, the approval must include the DAO-authorized signature.

(m) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) Canadian Airworthiness Directive CF–2016–08, dated March 30, 2016, for related information. This MCAI may be found in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–7427.

(2) For service information identified in this AD, contact Bombardier, Inc., 400 Côte-Vertu Road West, Dorval, Québec H4S 1Y9, Canada; telephone 514–855–5000; fax 514–855–7401; email *thd.crj@aero.bombardier.com;* Internet *http://www.bombardier.com.* You may view this service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Issued in Renton, Washington, on July 8, 2016.

Michael Kaszycki,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2016–16733 Filed 7–14–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2016–8178; Directorate Identifier 2015–NM–197–AD]

RIN 2120–AA64

Airworthiness Directives; Bombardier, Inc. Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for certain Bombardier, Inc. Model DHC–8–400 series airplanes. This proposed AD was prompted by a determination by the manufacturer that shims might not have been installed between certain longerons and longeron joint fittings. This proposed AD would require repetitive inspections of the external surface of the fuselage skin panel for loose or working fasteners, and corrective action if necessary; a detailed visual inspection of the longeron joint fittings for the existence of shims and, if necessary, repetitive inspections of the longeron and the longeron joint fittings for any cracking, and corrective action if necessary. This proposed AD would also provide terminating action for certain repetitive inspections. We are proposing this AD to detect and correct missing shims between the longerons and longeron joint fittings. Such missing shims could result in a gapping condition and lead to stress corrosion cracking of the longeron joint fittings, and could adversely affect the structural integrity of the wing-to-fuselage attachment joints.

DATES: We must receive comments on this proposed AD by August 29, 2016.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov*. Follow the instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.
- *Hand Delivery:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this NPRM, contact Bombardier, Inc., Q-Series Technical Help Desk, 123 Garratt Boulevard, Toronto, Ontario M3K 1Y5, Canada; telephone 416–375–4000; fax 416–375–4539; email *thd.qseries@aero.bombardier.com;* Internet *http://www.bombardier.com*. You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–8178; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Aziz Ahmed, Aerospace Engineer, Airframe and Mechanical Systems Branch, ANE–171, FAA, New York Aircraft Certification Office (ACO), 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7329; fax 516–794–5531.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include “Docket No. FAA–2016–8178; Directorate Identifier 2015–NM–197–AD” at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD based on those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

Discussion

Transport Canada Civil Aviation (TCCA), which is the aviation authority for Canada, has issued Canadian Airworthiness Directive CF–2015–22, dated August 3, 2015 (referred to after this as the Mandatory Continuing Airworthiness Information, or “the MCAI”), to correct an unsafe condition for certain Bombardier, Inc. Model DHC–8–400 series airplanes. The MCAI states:

> The aeroplane manufacturer has determined that shims may not have been installed between the longerons and longeron joint fittings at fuselage station X373–380, stringers 7 on the left and right hand side, on certain aeroplanes. The missing shims could result in a gapping condition and could lead to stress corrosion cracking of the longeron joint fittings.
>
> Failure of the longeron joint fitting could compromise the structural integrity of the wing-to-fuselage attachment joint.
>
> This [Canadian] AD mandates inspections in the area of the longeron joint fittings.

Corrective actions include replacing any loose or working fasteners (fasteners that show signs of wear or fatigue corrosion), repairing any structural damage, and replacing any cracked longeron or longeron with an amplitude of 50% or more of the calibration signal. You may examine the MCAI in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–8178.

Related Service Information Under 1 CFR Part 51

Bombardier, Inc. has issued Bombardier Service Bulletin 84–53–65, dated February 27, 2015. The service information describes procedures for inspections of the external surface of the fuselage skin panel for loose or working fasteners; a detailed visual inspection of the longeron joint fittings for the existence of shims; high frequency eddy current (HFEC) inspections of the longeron and the longeron joint fittings for any cracking; and replacement of longeron fittings, shims, and fasteners. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

FAA’s Determination and Requirements of This Proposed AD

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to our bilateral agreement with the State of Design Authority, we have been notified of the unsafe condition described in the MCAI and service information referenced above. We are proposing this AD because we evaluated all pertinent information and determined an unsafe condition exists and is likely to exist or develop on other products of the same type design.

Costs of Compliance

We estimate that this proposed AD affects 76 airplanes of U.S. registry.

We also estimate that it would take about 2 work-hours per product to comply with the basic requirements of this proposed AD. The average labor rate is $85 per work-hour. Based on these figures, we estimate the cost of this proposed AD on U.S. operators to be $12,920, or $170 per product.

In addition, we estimate that any necessary follow-on actions would take about 3 work-hours for the inspection for missing shims, 9 work-hours for the replacement of longeron fittings and shims, and 1 work-hour for a reporting requirement; and would require parts costing $3,222; for a cost of up to $4,327 per product. We have no way of determining the number of aircraft that might need these actions. We have received no definitive data that would enable us to provide cost estimates for repair of loose or working fasteners or structural damage specified in this proposed AD.

Paperwork Reduction Act

A federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB control number. The control number for the collection of information required by this proposed AD is 2120–0056. The paperwork cost associated with this proposed AD has been detailed in the Costs of Compliance section of this document and includes time for reviewing instructions, as well as completing and reviewing the collection of information. Therefore, all reporting associated with this proposed AD is mandatory. Comments concerning the accuracy of this burden and suggestions for reducing the burden should be directed to the FAA at 800 Independence Ave. SW., Washington, DC 20591, ATTN: Information Collection Clearance Officer, AES–200.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. "Subtitle VII: Aviation Programs," describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in "Subtitle VII, part A, subpart III, Section 44701: General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this proposed regulation:

1. Is not a "significant regulatory action" under Executive Order 12866;

2. Is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);

3. Will not affect intrastate aviation in Alaska; and

4. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

Bombardier, Inc.: Docket No. FAA–2016–8178; Directorate Identifier 2015–NM–197–AD.

(a) Comments Due Date

We must receive comments by August 29, 2016.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Bombardier, Inc. Model DHC–8–400, –401, and –402 airplanes, certificated in any category, serial numbers 4156 through 4453 inclusive, 4456, and 4457.

(d) Subject

Air Transport Association (ATA) of America Code 53, Fuselage.

(e) Reason

This AD was prompted by a determination by the manufacturer that shims might not have been installed between the longerons and longeron joint fittings at station X373–380, stringer 7, on the left and right sides of the airplane. We are issuing this AD to detect and correct missing shims between the longerons and longeron joint fittings. Such missing shims could result in a gapping condition and lead to stress corrosion cracking of the longeron joint fittings, and could adversely affect the structural integrity of the wing-to-fuselage attachment joints.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Inspection of the External Surface of the Fuselage Skin Panels

At the time specified in paragraph (g)(1) or (g)(2) of this AD, as applicable, do a detailed visual inspection of the external surface of the fuselage skin panel for loose or working fasteners (fasteners that show signs of wear or fatigue corrosion) and structural damage, in accordance with paragraph 3.B. of the Accomplishment Instructions of Bombardier Service Bulletin 84–53–65, dated February 27, 2015.

(1) For airplanes that have accumulated less than 10,000 total flight hours, or less than 5 years in service since new, as of the effective date of this AD: Prior to accumulating 12,000 total flight hours or 6 years in service since new, whichever occurs first.

(2) For airplanes that have accumulated 10,000 total flight hours or more, or 5 years or more in service since new, as of the effective date of this AD: Within 2,000 flight hours or 12 months after the effective date of this AD, whichever occurs first.

(h) Corrective Actions

If any loose or working fastener or any structural damage is found during any inspection required by this AD: Before further flight, repair using a method approved by the Manager, New York Aircraft Certification Office (ACO), FAA; or Transport Canada Civil Aviation (TCCA); or Bombardier, Inc.'s TCCA Design Approval Organization (DAO); and therafter do the inspections required by paragraph (i) of this AD. Accomplishment of a repair in accordance with a method approved by the Manager, New York ACO, FAA; or TCCA; or

Bombardier, Inc.'s TCCA DAO terminates the repetitive inspections required by paragraph (i) of this AD for the repaired area only.

(i) Repetitive Detailed Visual Inspections

Repeat the detailed visual inspection required by the introductory text to paragraph (g) of this AD at intervals not to exceed 12 months or 2,000 flight cycles, whichever occurs first after accomplishment of the most recent inspection, until the actions required by the introductory text to paragraph (j) of this AD are done.

(j) Inspection for Missing Shims

At the time specified in paragraph (j)(1) or (j)(2) of this AD, as applicable, do a detailed visual inspection of the longeron joint fittings for the existence of shims, in accordance with paragraph 3.C. of the Accomplishment Instructions of Bombardier Service Bulletin 84–53–65, dated February 27, 2015.

(1) For airplanes that have accumulated less than 10,000 total flight hours, or less than 5 years in service since new, as of the effective date of this AD: Prior to accumulating 18,000 total flight hours or 9 years in service since new, whichever occurs first.

(2) For airplanes that have accumulated 10,000 total flight hours or more, or 5 years or more in service since new, as of the effective date of this AD: Within 8,000 flight hours or 4 years after the effective date of this AD, whichever occurs first; but not to exceed 30,000 total flight hours or 144 months in service since new, whichever occurs first.

(k) Airplanes With Installed Shims: No Further Action Required

If the inspection required by the introductory text to paragraph (j) of this AD reveals that shims are installed in the longeron joint fittings, no further action is required by this AD.

(l) Airplanes With Missing Shims: High Frequency Eddy Current (HFEC) Inspections and Corrective Actions

If the inspection required by the introductory text to paragraph (j) of this AD reveals that any shim is missing from the longeron joint fittings: Before further flight, do an HFEC inspection of the longeron and the longeron joint fittings for any cracking, in accordance with paragraph 3.D. of the Accomplishment Instructions of Bombardier Service Bulletin 84–53–65, dated February 27, 2015.

(1) If any crack is found, or any indication is found with an amplitude of 50% or more of the calibration signal: Before further flight, replace the longeron joint fittings, in accordance with paragraph 3.E. of the Accomplishment Instructions of Bombardier Service Bulletin 84–53–65, dated February 27, 2015.

(2) After each inspection required by the introductory text to paragraph (l) and paragraph (l)(1) of this AD, report the inspection results at the applicable time specified in paragraph (l)(2)(i) or (l)(2)(ii) of this AD to Bombardier, Inc., Q-Series Technical Help Desk, 123 Garratt Boulevard, Toronto, Ontario M3K 1Y5, Canada; telephone 416–375–4000; fax 416–375–4539; email *thd.qseries@aero.bombardier.com;* Internet *http://www.bombardier.com.*

(i) If the inspection was done on or after the effective date of this AD: Within 30 days after that inspection.

(ii) If the inspection was done before the effective date of this AD: Within 30 days after the effective date of this AD.

(3) If any crack, or any indication with an amplitude of 50% or more of the calibration signal is not found: Repeat the HFEC inspection required by the introductory text to paragraph (l) of this AD at intervals not to exceed 12,000 flight hours or 6 years, whichever occurs first after accomplishment of the most recent HFEC inspection, in accordance with paragraph 3.D. of the Accomplishment Instructions of Bombardier Service Bulletin 84–53–65, dated February 27, 2015. If any crack is found, or any indication is found with an amplitude of 50% or more of the calibration signal: Before further flight, replace the longeron joint fittings, in accordance with paragraph 3.E. of the Accomplishment Instructions of Bombardier Service Bulletin 84–53–65, dated February 27, 2015.

(m) Terminating Action for Repetitive HFEC Inspections

Replacement of the longeron joint fittings, in accordance with paragraph 3.E. of the Accomplishment Instructions of Bombardier Service Bulletin 84–53–65, dated February 27, 2015, constitutes terminating action for the repetitive HFEC inspections required by paragraph (l)(3) of this AD.

(n) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, New York ACO, ANE–170, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the ACO, send it to ATTN: Program Manager, Continuing Operational Safety, FAA, New York ACO, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7300; fax 516–794–5531. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office. The AMOC approval letter must specifically reference this AD.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, New York ACO, ANE–170, FAA; or TCCA; or Bombardier, Inc.'s TCCA DAO. If approved by the DAO, the approval must include the DAO-authorized signature.

(3) *Reporting Requirements:* A federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB Control Number. The OMB Control Number for this information collection is 2120–0056. Public reporting for this collection of information is estimated to be approximately 5 minutes per response, including the time for reviewing instructions, completing and reviewing the collection of information. All responses to this collection of information are mandatory. Comments concerning the accuracy of this burden and suggestions for reducing the burden should be directed to the FAA at: 800 Independence Ave. SW., Washington, DC 20591, Attn: Information Collection Clearance Officer, AES–200.

(o) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) Canadian Airworthiness Directive CF–2015–22, dated August 3, 2015, for related information. This MCAI may be found in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–8178.

(2) For service information identified in this AD, contact Bombardier, Inc., Q-Series Technical Help Desk, 123 Garratt Boulevard, Toronto, Ontario M3K 1Y5, Canada; telephone 416–375–4000; fax 416–375–4539; email *thd.qseries@aero.bombardier.com;* Internet *http://www.bombardier.com.* You may view this service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Issued in Renton, Washington, on July 8, 2016.

Michael Kaszycki,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2016–16732 Filed 7–14–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2016–8177; Directorate Identifier 2015–NM–129–AD]

RIN 2120–AA64

Airworthiness Directives; Bombardier, Inc. Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for certain Bombardier, Inc. Model BD–700–1A10 and BD–700–1A11 airplanes. This proposed AD was prompted by a determination that the existing instruction in a certain task in the aircraft maintenance manual (AMM)

will not accomplish the intent of a certification maintenance requirement (CMR). This CMR task tests the pitch feel (PF) and rudder travel limiter actuator (RTLA) back-up modules in the flight control unit (FCU) to detect dormant failures. This proposed AD would require doing an operational test of the FCU back-up modules, and repair if necessary. We are proposing this AD to detect and correct a dormant failure of both FCU back-up modules. This condition, in combination with other failures in the FCU, may result in the inability to maintain the minimum control requirements for the PF and RTLA, which could create hazardous flight control inputs during flight.

DATES: We must receive comments on this proposed AD by August 29, 2016.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov*. Follow the instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.
- *Hand Delivery:*
- Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this NPRM, contact Bombardier, Inc., 400 Côte-Vertu Road West, Dorval, Québec H4S 1Y9, Canada; telephone 514–855–5000; fax 514–855–7401; email *thd.crj@aero.bombardier.com;* Internet *http://www.bombardier.com*. You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–8177; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Assata Dessaline, Aerospace Engineer, Avionics and Services Branch, ANE–172, FAA, New York Aircraft Certification Office (ACO), 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7301; fax 516–794–5531.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include "Docket No. FAA–2016–8177; Directorate Identifier 2015–NM–129–AD" at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD based on those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

Discussion

Transport Canada Civil Aviation (TCCA), which is the aviation authority for Canada, has issued Canadian Airworthiness Directive CF–2015–06R1, dated April 22, 2015 (referred to after this as the Mandatory Continuing Airworthiness Information, or "the MCAI"), to correct an unsafe condition for certain Bombardier, Inc. Model BD–700–1A10 and BD–700–1A11 airplanes. The MCAI states:

> It was discovered that the existing instruction in the Aircraft Maintenance Manual (AMM) Task 27–61–05–710–801 will not accomplish the intent of the Certification Maintenance Requirement (CMR) task number 27–61–05–201. This CMR task was required to test the Pitch Feel (PF) and Rudder Travel Limiter Actuator (RTLA) back-up modules in the Flight Control Unit (FCU) to detect dormant failures. If not detected, a dormant failure of both FCU back-up modules, in combination with other failures in the FCU, may result in the inability to maintain the Minimum Control Requirements for the PF and RTLA, which could create hazardous flight control inputs during flight.
>
> The original issue of this [Canadian] AD mandated the performance of an operational test of the FCU back-up modules using the proper AMM task instructions [and repair if necessary].
>
> Revision 1 of this [Canadian] AD is to correct the model number designation in the Applicability section.

You may examine the MCAI in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–8177.

Related Service Information Under 1 CFR Part 51

We reviewed the following service information. This service information describes procedures for doing an operational test of the FCU back-up modules.

- Bombardier Global 5000, BD–700 Aircraft Maintenance Manual—Part II, Temporary Revision No. 27–48, dated October 5, 2015.
- Bombardier Global 5000, GL 5000 FEATURING GLOBAL VISION FLIGHT DECK—Aircraft Maintenance Manual—Part II, Temporary Revision No. 27–24, dated October 5, 2015.
- Bombardier Global 6000, GL 6000 Aircraft Maintenance Manual—Part II, Temporary Revision No. 27–24, dated October 5, 2015.
- Bombardier Global Express, BD–700 Aircraft Maintenance Manual—Part II, Temporary Revision No. 27–78, dated October 5, 2015.
- Bombardier Global Express XRS, BD–700 Aircraft Maintenance Manual—Part II, Temporary Revision No. 27–47, dated October 5, 2015.

This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

FAA's Determination and Requirements of This Proposed AD

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to our bilateral agreement with the State of Design Authority, we have been notified of the unsafe condition described in the MCAI and service information referenced above. We are proposing this AD because we evaluated all pertinent information and determined an unsafe condition exists and is likely to exist or develop on other products of the same type design.

Differences Between This Proposed AD and the MCAI or Service Information

The MCAI specifies accomplishing an operational test of the FCU back-up modules, but does not specify a corrective action if the test is failed. If any FCU fails any operational test, this proposed AD would require repair using a method approved by the Manager, New York Aircraft Certification Office (ACO), ANE–170, FAA; or TCCA; or

Bombardier, Inc.'s TCCA Design Approval Organization (DAO).

Costs of Compliance

We estimate that this proposed AD affects 76 airplanes of U.S. registry.

We also estimate that it would take about 3 work-hours per product to comply with the basic requirements of this proposed AD. The average labor rate is $85 per work-hour. Based on these figures, we estimate the cost of this proposed AD on U.S. operators to be $19,380, or $255 per product.

We have received no definitive data that would enable us to provide cost estimates for the on-condition actions specified in this NPRM.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. "Subtitle VII: Aviation Programs," describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in "Subtitle VII, Part A, Subpart III, Section 44701: General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this proposed regulation:

1. Is not a "significant regulatory action" under Executive Order 12866;
2. Is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);
3. Will not affect intrastate aviation in Alaska; and
4. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

Bombardier, Inc.: Docket No. FAA–2016–8177; Directorate Identifier 2015–NM–129–AD.

(a) Comments Due Date

We must receive comments by August 29, 2016.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Bombardier, Inc. Model BD–700–1A10 and BD–700–1A11 airplanes, certificated in any category, serial numbers 9002 and subsequent.

(d) Subject

Air Transport Association (ATA) of America Code 27, Flight controls.

(e) Reason

This AD was prompted by a determination that the existing instruction in a certain task in the aircraft maintenance manual (AMM) will not accomplish the intent of a certification maintenance requirement (CMR). This CMR task tests the pitch feel (PF) and rudder travel limiter actuator (RTLA) back-up modules in the flight control unit (FCU) to detect dormant failures. We are issuing this AD to detect and correct a dormant failure of both FCU back-up modules. This condition, in combination with other failures in the FCU, may result in the inability to maintain the minimum control requirements for the PF and RTLA, which could create hazardous flight control inputs during flight.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) FCU Operational Test

(1) For airplanes with an FCU that has accumulated 3,000 total flight hours or more as of the effective date of this AD: Within 15 months or 700 hours flight hours, whichever occurs first, after the effective date of this AD, do an operational test of the FCU back-up modules, in accordance with the applicable service information specified in paragraph (h) of this AD.

(2) For airplanes with an FCU that has accumulated less than 3,000 hours total flight hours as of the effective date of this AD, and on which an operational test has been accomplished as specified in AMM Task 27–61–05–710–801 prior to the applicable AMM revisions specified in paragraph (i) of this AD: Within 15 months or 700 hours flight hours, whichever occurs first, after the effective date of this AD, do an operational test of the FCU back-up modules, in accordance with the applicable service information specified in paragraph (h) of this AD.

(3) For airplanes with an FCU that has accumulated less than 3,000 total flight hours as of the effective date of this AD, and on which an operational test has not been accomplished as specified in AMM task 27–61–05–710–801: Before the FCU accumulates 3,000 total flight hours, perform an operational test of the FCU back-up modules, in accordance with the applicable service information specified in paragraph (h) of this AD.

(h) Service Information for Accomplishing Paragraph (g) of This AD

Do the actions required by paragraph (g) of this AD in accordance with the applicable service information specified in paragraphs (h)(1) through (h)(5) of this AD.

(1) Bombardier Global 5000, BD–700 Aircraft Maintenance Manual—Part II, Temporary Revision No. 27–48, dated October 5, 2015.

(2) Bombardier Global 5000 FEATURING GLOBAL VISION FLIGHT DECK, GL 5000 Aircraft Maintenance Manual—Part II, Temporary Revision No. 27–24, dated October 5, 2015.

(3) Bombardier Global 6000, GL 6000 Aircraft Maintenance Manual—Part II, Temporary Revision No. 27–24, dated October 5, 2015.

(4) Bombardier Global Express, BD–700 Aircraft Maintenance Manual—Part II, Temporary Revision No. 27–78, dated October 5, 2015.

(5) Bombardier Global Express ERS, BD0700 Airplane Maintenance Manual—Part II, Temporary Revision No. 27–47, dated October 5, 2015.

(i) AMM Revisions Referred to in Paragraph (g)(2) of This AD

The following AMM revisions are used to comply with paragraph (g)(2) of this AD.

(1) For Model BD–700–1A10 airplanes: Use the AMM revision specified in paragraph (i)(1)(i), (ii), or (iii), as applicable.

(i) Bombardier Global Express GL700 AMM—Part II, Revision 61, dated March 3, 2014.

(ii) Bombardier Global Express GL XRS AMM—Part II, Revision 39, dated March 3, 2014.

(iii) Bombardier Global Express GL 6000 AMM—Part II, Revision 9, dated March 3, 2014.

(2) For Model BD–700–1A11 airplanes: Use Bombardier Global Express GL 5000 AMM—Part II, Revision 42, dated March 3, 2014; or

GL 5000 GVFD AMM—Part II, Revision 9, dated March 3, 2014; as applicable.

(j) Corrective Action

If any FCU fails any operational test required by this AD: Before further flight, repair using a method approved by the Manager, New York ACO, ANE–170, FAA; or Transport Canada Civil Aviation (TCCA); or Bombardier, Inc.'s TCCA Design Approval Organization (DAO).

(k) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, New York Aircraft Certification Office (ACO), ANE–170, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the ACO, send it to ATTN: Program Manager, Continuing Operational Safety, FAA, New York ACO, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7300; fax 516–794–5531. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office. The AMOC approval letter must specifically reference this AD.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, New York ACO, ANE–170, FAA; or TCCA; or Bombardier, Inc.'s TCCA DAO. If approved by the DAO, the approval must include the DAO-authorized signature.

(l) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) Canadian Airworthiness Directive CF–2015–06R1, dated April 22, 2015, for related information. This MCAI may be found in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–8177.

(2) For service information identified in this AD, contact Bombardier, Inc., 400 Côte-Vertu Road West, Dorval, Québec H4S 1Y9, Canada; telephone 514–855–5000; fax 514–855–7401; email *thd.crj@aero.bombardier.com;* Internet *http://www.bombardier.com.* You may view this service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Issued in Renton, Washington, on July 8, 2016.

Michael Kaszycki,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2016–16731 Filed 7–14–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2016–6692; Directorate Identifier 2016–NE–13–AD]

RIN 2120–AA64

Airworthiness Directives; Rolls-Royce plc Turbofan Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for all Rolls-Royce plc (RR) RB211–Trent 875–17, RB211–Trent 877–17, RB211–Trent 884–17, RB211–Trent 884B–17, RB211–Trent 892–17, RB211–Trent 892B–17, and RB211–Trent 895–17 turbofan engines. This proposed AD was prompted by a report of cracking and material release from an engine upper bifurcation fairing. This proposed AD would require repetitive inspections of the engine upper bifurcation fairing and repairing or replacing any fairing that fails inspection. We are proposing this AD to prevent failure of the engine fire protection system, engine fire, and damage to the airplane.

DATES: We must receive comments on this NPRM by September 13, 2016.

ADDRESSES: You may send comments by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* 202–493–2251.

For service information identified in this proposed AD, contact Rolls-Royce plc, Corporate Communications, P.O. Box 31, Derby, England, DE24 8BJ; phone: 011–44–1332–242424; fax: 011–44–1332–249936; email: *http://www.rolls-royce.com/contact/civil_team.jsp;* Internet: *https://customers.rolls-royce.com/public/rollsroycecare.* You may view this service information at the FAA, Engine & Propeller Directorate, 1200 District Avenue, Burlington, MA. For information on the availability of this material at the FAA, call 781–238–7125.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–6692; or in person at the Docket Operations office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the mandatory continuing airworthiness information (MCAI), the regulatory evaluation, any comments received, and other information. The address for the Docket Office (phone: 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Wego Wang, Aerospace Engineer, Engine Certification Office, FAA, Engine & Propeller Directorate, 1200 District Avenue, Burlington, MA 01803; phone: 781–238–7134; fax: 781–238–7199; email: *wego.wang@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this NPRM. Send your comments to an address listed under the **ADDRESSES** section. Include "Docket No. FAA–2016–6692; Directorate Identifier 2016–NE–13–AD" at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this NPRM. We will consider all comments received by the closing date and may amend this NPRM based on those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact with FAA personnel concerning this NPRM.

Discussion

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Community, has issued EASA AD 2016–0084, dated April 28, 2016 (referred to hereinafter as "the MCAI"), to correct an unsafe condition for the specified products. The MCAI states:

> Inspection of in-service Rolls-Royce RB211 Trent 800 engines has identified cracking and/or material release from the upper bifurcation fairing. This fairing hardware mates to the aeroplane thrust reverser upper bifurcation forward fire seal. Both sets of hardware create the engine firewall to isolate the engine compartment fire zone, which is a firewall feature of the aeroplane type design. Damage (missing materials and holes/

openings) to the upper bifurcation fairing creates a breach of the engine fire wall, which may decrease the effectiveness of the engine fire detection and suppression systems due to excess fan air entering the engine compartment fire zone. This could delay or prevent the fire detection and suppression system from functioning properly, and can result in an increased risk of prolonged burning, potentially allowing a fire to reach unprotected areas of the engine, strut and wing.

Failure to inspect the engine upper bifurcation fairing as proposed by this AD could result in failure of the engine fire protection system, engine fire, and damage to the airplane.

You may obtain further information by examining the MCAI in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–6692.

Related Service Information

RR has issued Alert Non-Modification Service Bulletin (NMSB) RB.211–72–AJ165, dated March 31, 2016. The NMSB describes procedures for inspecting and, if necessary, repairing or replacing the engine upper bifurcation fairing.

FAA's Determination and Requirements of This Proposed AD

This product has been approved by the aviation authority of the United Kingdom and is approved for operation in the United States. Pursuant to our bilateral agreement with the European Community, EASA has notified us of the unsafe condition described in the MCAI and service information referenced above. We are proposing this AD because we evaluated all information provided by EASA and determined the unsafe condition exists and is likely to exist or develop on other products of the same type design. This NPRM would require repetitive inspections of the engine upper bifurcation fairing and repairing or replacing any fairing that fails inspection.

Costs of Compliance

We estimate that this proposed AD affects 125 engines installed on airplanes of U.S. registry. We estimate that it would take about 3.25 hours to inspect the upper bifurcation fairing do the inspection. We estimate that 5 engine fairings will require repair at 8 hours per engine and that an additional 5 engine fairings will require replacement at 30 hours per engine. We also estimate that materials and parts costs would be $500 for each engine. The cost for repair or replacement would be about $5,900 or $15,250 respectively. The average labor rate is $85 per hour. Based on these figures, we estimate the cost of this proposed AD on U.S. operators to be $55,681.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. "Subtitle VII: Aviation Programs," describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in "Subtitle VII, Part A, Subpart III, Section 44701: General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this proposed regulation:

(1) Is not a "significant regulatory action" under Executive Order 12866,

(2) Is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),

(3) Will not affect intrastate aviation in Alaska to the extent that it justifies making a regulatory distinction, and

(4) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

Rolls-Royce plc: Docket No. FAA–2016–6692; Directorate Identifier 2016–NE–13–AD.

(a) Comments Due Date

We must receive comments by September 13, 2016.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Rolls-Royce plc (RR) RB211–Trent 875–17, RB211–Trent 877–17, RB211–Trent 884–17, RB211–Trent 884B–17, RB211–Trent 892–17, RB211–Trent 892B–17, and RB211–Trent 895–17 turbofan engines.

(d) Reason

This AD was prompted by a report of cracking and material release from an engine upper bifurcation fairing. We are issuing this AD to prevent failure of the engine fire protection system, engine fire, and damage to the airplane.

(e) Actions and Compliance

Comply with this AD within the compliance times specified, unless already done.

(1) Within 7,500 engine flight hours (EFHs) time since new, or since last inspection, or within 150 flight cycles after the effective date of this AD, whichever occurs later, inspect the engine upper bifurcation fairing for cracks or missing material. Use paragraph (e)(3) of this AD to perform the inspections.

(2) Repeat the inspection required by this AD within every 7,500 EFH time since last inspection.

(3) Inspect the engine upper bifurcation fairing as follows. Refer to Figure 1 of RR Alert Non-Modification Service Bulletin (NMSB) RB.211–72–AJ165, dated March 31, 2016, for guidance on upper bifurcation fairing inspection locations.

(i) Visually inspect upper bifurcation fairing seal face 22, seal support 23, and zone A for any cracks or material loss on the right side.

(A) If fairing seal face 22 is found to have released material, repair or replace the fairing before further flight.

(B) If there is a single crack found on fairing seal face 22, shorter than 6 mm, repair or replace the fairing within 100 engine flight cycles, or at the next shop visit, whichever occurs sooner.

(C) If there is a single crack found on fairing seal face 22, longer than 6 mm, repair or replace the fairing within 15 engine flight cycles or at the next shop visit, whichever occurs sooner.

(D) If there are two or more cracks found on fairing seal face 22, replace the fairing within 15 engine flight cycles or at next shop visit, whichever occurs sooner.

(E) If there is any cracking or material loss found on seal support 23, replace the fairing within 15 engine flight cycles or at next shop visit, whichever occurs sooner.

(ii) If the visual inspection required by paragraph (e)(3)(i) of this AD does not detect any crack, fluorescent penetrant inspect zone A. Refer to AMM TASK 70–20–02, Water Washable Fluorescent Penetrant Inspection (Maintenance Process 213), or OMat 632, high sensitivity fluorescent penetrant inspection, for guidance on fluorescent penetrant inspection.

(A) If a crack shorter than 6 mm is detected, repair or replace the fairing within 100 engine flight cycles, or at the next shop visit, whichever occurs sooner.

(B) If a crack longer than 6 mm is detected, repair or replace the fairing within 15 engine flight cycles or at the next shop visit, whichever occurs sooner.

Definition

For the purpose of this AD, a "shop visit" is defined as induction of an engine into the shop for maintenance involving the separation of pairs of major mating engine flanges, except that the separation of engine flanges solely for the purposes of transportation without subsequent engine maintenance does not constitute an engine shop visit.

(f) Alternative Methods of Compliance (AMOCs)

The Manager, Engine Certification Office, FAA, may approve AMOCs for this AD. Use the procedures found in 14 CFR 39.19 to make your request. You may email your request to: *ANE-AD-AMOC@faa.gov*.

(g) Related Information

(1) For more information about this AD, contact Wego Wang, Aerospace Engineer, Engine Certification Office, FAA, Engine & Propeller Directorate, 1200 District Avenue, Burlington, MA 01803; phone: 781–238–7134; fax: 781–238–7199; email: *wego.wang@faa.gov*.

(2) Refer to MCAI European Aviation Safety Agency AD 2016–0084, dated April 28, 2016, for more information. You may examine the MCAI in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating it in Docket No. FAA–2016–6692.

(3) RR NMSB RB.211–72–AJ165, dated March 31, 2016, can be obtained from RR, using the contact information in paragraph (g)(4) of this proposed AD.

(4) For service information identified in this proposed AD, contact Rolls-Royce plc, Corporate Communications, P.O. Box 31, Derby, England, DE24 8BJ; phone: 011–44–1332–242424; fax: 011–44–1332–249936; email: *http://www.rolls-royce.com/contact/civil_team.jsp;* Internet: *https://customers.rolls-royce.com/public/rollsroycecare*.

(5) You may view this service information at the FAA, Engine & Propeller Directorate, 1200 District Avenue, Burlington, MA. For information on the availability of this material at the FAA, call 781–238–7125.

Issued in Burlington, Massachusetts, on July 1, 2016.

Ann C. Mollica,

Acting Manager, Engine & Propeller Directorate, Aircraft Certification Service.

[FR Doc. 2016–16646 Filed 7–14–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2016–8501; Directorate Identifier 2014–SW–042–AD]

RIN 2120–AA64

Airworthiness Directives; Sikorsky Aircraft Corporation Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for Sikorsky Aircraft Corporation (Sikorsky) Model S–92A helicopters. This proposed AD would require inspecting the main transmission forward (fwd) and aft frame assembly and adjacent skins for a crack and loose fasteners and establishing life limits for certain frame assemblies. This proposed AD is prompted by fatigue analysis indicating stress concentrations as well as the discovery of a crack in the station (STA) 362 frame and skin on a Model S–92A helicopter. The proposed actions are intended to detect a crack in a frame assembly and prevent failure of a frame and subsequent loss of control of the helicopter.

DATES: We must receive comments on this proposed AD by September 13, 2016.

ADDRESSES: You may send comments by any of the following methods:

- *Federal eRulemaking Docket:* Go to *http://www.regulations.gov*. Follow the online instructions for sending your comments electronically.
- *Fax:* 202–493–2251.
- *Mail:* Send comments to the U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590–0001.
- *Hand Delivery:* Deliver to the "Mail" address between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–8501; or in person at the Docket Operations Office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the economic evaluation, any comments received, and other information. The street address for the Docket Operations Office (telephone 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

For service information identified in this proposed AD, contact Sikorsky Aircraft Corporation, Customer Service Engineering, 124 Quarry Road, Trumbull, CT 06611; telephone 1–800-Winged-S or 203–416–4299; email *sikorskywcs@sikorsky.com*. You may review the referenced service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, Texas 76177.

FOR FURTHER INFORMATION CONTACT: Kristopher Greer, Aviation Safety Engineer, Boston Aircraft Certification Office, Engine & Propeller Directorate, 1200 District Avenue, Burlington, Massachusetts 01803; telephone (781) 238–7799; email *Kristopher.Greer@faa.gov*.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to participate in this rulemaking by submitting written comments, data, or views. We also invite comments relating to the economic, environmental, energy, or federalism impacts that might result from adopting the proposals in this document. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. To ensure the docket does not contain duplicate comments, commenters should send only one copy of written comments, or if comments are filed electronically, commenters should submit only one time.

We will file in the docket all comments that we receive, as well as a report summarizing each substantive public contact with FAA personnel concerning this proposed rulemaking. Before acting on this proposal, we will consider all comments we receive on or before the closing date for comments. We will consider comments filed after the comment period has closed if it is possible to do so without incurring expense or delay. We may change this proposal in light of the comments we receive.

Discussion

We propose to adopt a new AD for Sikorsky Model S–92A helicopters with certain part-numbered frame assemblies installed. This proposed AD is prompted by a fatigue analysis that indicates stress concentrations may develop at the steel doublers on the main transmission airframe support structure top deck, adjacent to the transmission feet. Additionally, a helicopter was discovered with a crack in the STA 362 frame and skin. This proposed AD would require inspecting the main transmission fwd and aft frame assemblies and adjacent skins for a crack and loose fasteners and replacing or repairing any cracked part or loose fastener. This proposed AD would also require establishing life limits for certain frame assemblies. The proposed actions are intended to detect a crack in the frame assemblies and to prevent failure of the main transmission frame assemblies and subsequent loss of control of the helicopter.

FAA's Determination

We are proposing this AD because we evaluated all known relevant information and determined that an unsafe condition exists and is likely to exist or develop on other helicopters of the same type design.

Related Service Information

Sikorsky issued S–92 Alert Service Bulletin (ASB) 92–53–008, Basic Issue, dated June 13, 2012 (ASB 92–53–008); S–92 ASB 92–53–009, Basic Issue, dated December 6, 2012 (ASB 92–53–009); and S–92 ASB 92–53–012, Basic Issue, dated February 10, 2014 (ASB 92–53–012). ASB 92–53–008 provides procedures for a one-time inspection of the main transmission frames and beams for a crack, missing or loose fastener or collar, damage, deformation, and corrosion. ASB 92–53–009 specifies an inspection before the first flight of the day and a recurring 150-hour inspection of the interior and exterior surfaces of the upper flanges and beams. ASB 92–53–012 specifies altering the fwd and aft transmission support frames by replacing the fasteners in accordance with Sikorsky Special Service Instructions No. 92–074–E, Revision E, dated April 9, 2014. After this alteration, the parts are re-identified with a new part number. Sikorsky refers to this alteration as a service life extension program modification.

Proposed AD Requirements

This proposed AD would establish a life limit for certain part-numbered frame assemblies by removing from service any part that has reached or exceeded its new life limit. Frame assemblies that are altered under Sikorsky's service life extension program and re-identified with a new part number must be removed from service upon accumulating the life limit of the old part-number or within certain hours TIS since the alteration, whichever occurs first.

This proposed AD would also require, for helicopters with certain part-numbered frame assemblies, within 24 clock-hours and thereafter before the first flight of each day or at intervals not to exceed 24 clock-hours, whichever occurs later, inspecting the top deck skin, straps, and fasteners for a crack and loose fasteners in two locations. If there is a loose fastener or a crack, this proposed AD would require repairing or replacing the cracked or loose part and performing additional inspections of the STA 328 frame, STA 362 frame, and the butt line (BL) 16.5 beams.

Finally, this proposed AD would require repetitively inspecting the STA 328 frame, STA 362 frame, and the BL 16.5 beams once the frame assembly exceeds certain hours TIS.

Differences Between This Proposed AD and the Service Information

The service information requires providing certain information to Sikorsky and this proposed AD would not. The service information specifies performing a fluorescent penetrant inspection if there is a suspected crack and contacting Sikorsky if there is a crack, while this proposed AD would only require repairing or replacing any cracked part. Contacting Sikorsky would not be required.

Costs of Compliance

We estimate that this proposed AD would affect 80 helicopters of U.S. Registry.

We estimate that operators may incur the following costs to comply with this AD. Labor costs are estimated at $85 per work-hour. We estimate a minimal cost to establish and revise the life limit of the frame assembly. We estimate it would take 1 work-hour to visually inspect the skin and 1 work-hour to inspect STA 328 and 362 frames. No parts would be needed for a total cost of $6,800 for the fleet for each inspection per inspection cycle. If a fastener is replaced, we estimate the cost to be minimal. If a frame is replaced, it would take 3,360 work-hours and a required parts cost of $296,000 for a total cost of $581,600 per helicopter.

Regulatory Findings

We determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed, I certify this proposed regulation:

1. Is not a "significant regulatory action" under Executive Order 12866;
2. Is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);
3. Will not affect intrastate aviation in Alaska to the extent that it justifies making a regulatory distinction; and
4. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared an economic evaluation of the estimated costs to comply with this proposed AD and placed it in the AD docket.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

Sikorsky Aircraft Corporation: Docket No. FAA–2016–8501; Directorate Identifier 2014–SW–042–AD.

(a) Applicability

This AD applies to Model S–92A helicopters, certificated in any category, with a forward (fwd) station (STA) 328 or aft STA 362 frame assembly with a part number (P/N) as shown in Table 1 to paragraph (e)(1), Table 2 to paragraph (e)(1), Table 3 to paragraph (e)(2), or Table 4 to paragraph (e)(3) of this AD.

(b) Unsafe Condition

This AD defines the unsafe condition as a crack in a main transmission airframe support structure. This condition could result in failure of a main transmission frame and subsequent loss of control of the helicopter.

(c) Comments Due Date

We must receive comments by September 13, 2016.

(d) Compliance

You are responsible for performing each action required by this AD within the specified compliance time unless it has already been accomplished prior to that time.

(e) Required Actions

(1) For helicopters with a frame assembly with a P/N shown in Table 1 to paragraph (e)(1) or Table 2 to paragraph (e)(1) of this AD, before further flight, remove from service any part that has reached or exceeded its new life limit. Fwd STA 328 frame assemblies that are altered and changed to P/N 92070–20124–064, 92070–20124–067, 92070–20127–045, 92070–20124–065, 92070–20124–047, or 92070–20127–046 must be removed from service upon accumulating 12,000 hours TIS from the alteration or 28,500 hours TIS total (regardless of P/N), whichever occurs first.

TABLE 1 TO PARAGRAPH (e)(1)

	Life limit hours TIS
Fwd STA 328 frame assembly P/N:	
92070–20124–064	12,000
92070–20124–067	12,000
92070–20127–045	12,000
92070–20124–065	12,000
92070–20124–047	12,000
92070–20127–046	12,000
92070–20124–063	12,000
92070–20124–066	12,000
92070–20127–041	12,000
Aft STA 362 frame assembly P/N:	
92070–20124–041	10,400
92070–20124–044	10,400
92070–20127–042	10,400
92070–20124–042	10,400
92070–20124–045	10,400
92070–20127–049	10,400
92070–20124–043	10,400
92070–20124–046	10,400
92070–20127–050	10,400
92070–20141–050	17,000
92070–20141–051	17,000
92070–20141–052	17,000

TABLE 2 TO PARAGRAPH (e)(1)

	Life limit hours TIS
Fwd STA 328 frame assembly P/N:	
92070–20097–058	28,500
92080–20047–047	28,500
92070–20097–060	28,500
92080–20047–048	28,500

(2) For helicopters with a frame assembly with a P/N shown in Table 1 to paragraph (e)(1), Table 2 to paragraph (e)(1), or Table 3 to paragraph (e)(2) of this AD: Within 24 clock-hours, and thereafter before the first flight of each day or at intervals not to exceed 24 clock-hours, whichever occurs later, using a 10X or higher power magnifying glass, inspect the skin, straps, and fasteners of the top deck for a crack and loose fasteners in two locations from the STA 328 frame to the STA 305 frame between the right butt line (BL) 16.5 beam and the left BL 16.5 beam, and from the STA 362 frame to the STA 379 frame between the right BL 16.5 beam and the left BL 16.5 beam. If there is a loose fastener or a crack:

(i) Repair or replace any cracked part and any loose fastener before further flight.

(ii) Inspect the STA 328 frame and STA 362 frame between the left and right BL16.5 beams and inspect the area on the left and right BL 16.5 beams six inches on either side of the mounting pads for a crack and loose fasteners. If there is a loose fastener or a crack, repair or replace any cracked part and any loose fastener before further flight.

(iii) Inspect the STA 328 and STA 362 outboard frames, left and right sides, from the BL 16.5 beam to water line 252.25 for a crack and loose fasteners. If there is a loose fastener or a crack, repair or replace any cracked part and any loose fastener before further flight.

TABLE 3 TO PARAGRAPH (e)(2)

Fwd STA 328 frame assembly P/N	Aft STA 362 frame assembly P/N
92209–02106–042	92070–20097–062
92209–02106–043	92080–20047–051
92070–20097–041	92209–02109–043
92080–20047–041	92209–02109–044
	92070–20097–042
	92080–20047–042
	92070–20097–064
	92080–20047–052

(3) For each frame assembly listed in Table 1 to paragraph (e)(1) or Table 4 to paragraph (e)(3) of this AD with 1,801 or more hours TIS, and for each frame assembly listed in Table 2 to paragraph (e)(1) or Table 3 to paragraph (e)(2) of this AD with 1,301 or more hours TIS, within 150 hours TIS and thereafter at intervals not to exceed 150 hours TIS, perform the inspections in paragraphs (e)(2)(ii) and (e)(2)(iii) of this AD.

TABLE 4 TO PARAGRAPH (e)(3)

Fwd STA 328 frame assembly P/N	Aft STA 362 frame assembly P/N
92209–02107–042	92070–02108–042
92209–02107–103	92080–02108–103

(f) Alternative Methods of Compliance (AMOC)

(1) The Manager, Boston Aircraft Certification Office, FAA, may approve AMOCs for this AD. Send your proposal to: Kristopher Greer, Aviation Safety Engineer, Engine & Propeller Directorate, 1200 District Avenue, Burlington, Massachusetts 01803; telephone (781) 238–7799; email *Kristopher.Greer@faa.gov.*

(2) For operations conducted under a 14 CFR part 119 operating certificate or under 14 CFR part 91, subpart K, we suggest that you notify your principal inspector, or lacking a principal inspector, the manager of the local flight standards district office or certificate holding district office before operating any aircraft complying with this AD through an AMOC.

(g) Additional Information

Sikorsky S–92 Alert Service Bulletin (ASB) 92–53–008, Basic Issue, dated June 13, 2012; ASB 92–53–009, Basic Issue, dated December 6, 2012; ASB 92–53–012, Basic Issue, dated February 10, 2014, and Sikorsky Special Service Instructions No. 92–074–E, Revision E, dated April 9, 2014, which are not incorporated by reference, contain additional information about the subject of this AD. For service information identified in this AD, contact Sikorsky Aircraft Corporation, Customer Service Engineering, 124 Quarry Road, Trumbull, CT 06611; telephone 1–800–Winged–S or 203–416–4299; email *sikorskywcs@sikorsky.com.*

You may review a copy of information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, Texas 76177.

(h) Subject

Joint Aircraft Service Component (JASC) Code: 5311 Fuselage Main, Frame.

Issued in Fort Worth, Texas, on July 7, 2016.

Scott A. Horn,

Acting Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 2016–16749 Filed 7–14–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–134016–15]

RIN 1545–BN47

Guidance Under Section 355 Concerning Device and Active Trade or Business

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document contains proposed regulations under section 355 of the Internal Revenue Code (Code). The proposed regulations would clarify the application of the device prohibition and the active business requirement of section 355. The proposed regulations would affect corporations that distribute the stock of controlled corporations, their shareholders, and their security holders.

DATES: Written or electronic comments and requests for a public hearing must be received by October 13, 2016.

ADDRESSES: Send submissions to: CC:PA:LPD:PR (REG–134016–15), Room 5203, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20224. Submissions may be hand-delivered Monday through Friday between the hours of 8 a.m. and 4 p.m. to: CC:PA:LPD:PR (REG–134016–15), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue NW., Washington, DC 20224. Submissions may also be sent electronically via the Federal eRulemaking Portal at *http://www.regulations.gov* (IRS REG–134016–15).

FOR FURTHER INFORMATION CONTACT: Concerning the proposed regulations, Stephanie D. Floyd or Russell P. Subin at (202) 317–6848; concerning submissions of comments and/or requests for a public hearing, Regina Johnson at (202) 317–6901 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Background

A. Introduction

This document contains proposed regulations that would amend 26 CFR part 1 under section 355 of the Code. The proposed regulations would provide additional guidance regarding the device prohibition of section 355(a)(1)(B) and provide a minimum threshold for the assets of one or more active trades or businesses, within the meaning of section 355(a)(1)(C) and (b), of the distributing corporation and each controlled corporation (in each case, within the meaning of section 355(a)(1)(A)).

This Background section of the preamble (1) summarizes the requirements of section 355, (2) discusses the development of current law and IRS practice under section 355 and the regulations thereunder, and (3) explains the reasons for the proposed regulations.

B. Section 355 Requirements

Generally, if a corporation distributes property with respect to its stock to a shareholder, section 301(b) provides that the amount of the distribution is equal to the amount of money and the fair market value of other property received. Under section 301(c), this amount is treated as (1) the receipt by the shareholder of a dividend to the extent of the corporation's earnings and profits, (2) the recovery of the shareholder's basis in the stock, and/or (3) gain from the sale or exchange of property. The corporation recognizes gain under section 311(b) to the extent the fair market value of the property distributed exceeds the corporation's adjusted basis in the property. However, section 355 provides that, under certain circumstances, a corporation (Distributing) may distribute stock and securities in a corporation it controls within the meaning of section 368(c) (Controlled) to its shareholders and security holders without causing either Distributing or its shareholders or security holders to recognize income, gain, or loss on the distribution.

Section 355 has numerous requirements for a distribution to be tax-free to Distributing and its shareholders. Some of these requirements are intended to prevent a distribution from being used inappropriately to avoid shareholder-level tax on dividend income. As examples, section 355(a)(1)(B) provides that the transaction must not be used principally as a device for the distribution of the earnings and profits of Distributing or Controlled or both (a device), and section 355(a)(1)(C) and (b) require Distributing and Controlled each to be engaged, immediately after the distribution, in the active conduct of a trade or business (an active business). To qualify for this purpose, an active business must have been actively conducted throughout the five-year period ending on the date of the distribution and must not have been acquired, directly or indirectly, within this period in a transaction in which gain or loss was recognized. Section 355(b)(2)(B), (C), and (D).

Distributions of the stock of Controlled generally take three different forms: (1) A pro rata distribution to Distributing's shareholders of the stock of Controlled (a spin-off), (2) a distribution of the stock of Controlled in redemption of Distributing stock (a split-off), or (3) a liquidating distribution in which Distributing distributes the stock of more than one Controlled, either pro rata or non-pro rata (in either case, a split-up).

C. Development of Current Law and IRS Practice

1. Early Legislation

The earliest predecessor of section 355 was section 202(b) of the Revenue Act of 1918, ch. 18 (40 Stat. 1057, 1060), which permitted a tax-free exchange by a shareholder of stock in a corporation for stock in another corporation in connection with a reorganization. This section did not allow tax-free spin-offs. In section 203(c) of the Revenue Act of 1924, ch. 234 (43 Stat. 253, 256), Congress amended this provision to allow tax-free spin-offs pursuant to plans of reorganization.

Taxpayers tried to use this provision to avoid the dividend provisions of the Code by having Distributing contribute surplus cash or liquid assets to a newly formed Controlled and distribute the Controlled stock to its shareholders. *See, e.g.,Gregory* v. *Helvering,* 293 U.S. 465 (1935). Congress reacted to this abuse by eliminating the spin-off provision in the Revenue Act of 1934, ch. 277 (48 Stat. 680). The legislative history states that the provision had provided a method for corporations "to pay what would otherwise be taxable dividends, without any taxes upon their shareholders" and that "this means of avoidance should be ended." H.R. Rep. No. 73–704, at 14 (1934).

In section 317(a) of the Revenue Act of 1951, ch. 521 (65 Stat. 452, 493), Congress re-authorized spin-offs pursuant to plans of reorganization:

> . . . unless it appears that (A) any corporation which is a party to such reorganization was not intended to continue the active conduct of a trade or business after such reorganization, or (B) the corporation whose stock is distributed was used principally as a device for the distribution of earnings and profits to the shareholders of any corporation a party to the reorganization.

During debate on this legislation, Senator Hubert Humphrey expressed concerns about spin-offs and argued that these restrictions were necessary. *See, e.g.,* 97 Cong. Rec. 11812 (1951) ("Unless strictly safeguarded, [a spin-off provision] can result in a loophole that will enable a corporation to distribute earnings and profits to stockholders without payment of the usual income taxes."); *Id.* ("Clauses (A) and (B) of section 317 provide very important safeguards against the tax avoidance which would be possible if section 317 were adopted without clauses (A) and (B)."). *See also* 96 Cong. Rec. 13686 (1950) ("It was the viewpoint of the committee that [a spin-off] must be strictly a bona fide transaction, not colorable, not for the purpose of evading the tax.").

Until 1954, a spin-off, split-off, or split-up was eligible for tax-free treatment only if Distributing transferred property to Controlled as part of a reorganization. In 1954, Congress adopted section 355 as part of the 1954 Code. As a significant innovation, section 355 allowed spin-offs, split-offs, and split-ups to be tax-free without a reorganization, and this innovation remains in effect.

2. Case Law

Courts applying section 355 (or a predecessor provision) have generally placed greater emphasis on the substance of the transaction than on compliance with the technical requirements of the statute. Thus, some courts have determined that a transaction does not qualify under section 355 (or a predecessor provision), notwithstanding strict statutory compliance, on the basis that the substance of the transaction was inconsistent with congressional intent. For example, in *Gregory,* the Supreme Court held that compliance with the letter of the spin-off statute was insufficient if the transaction was otherwise indistinguishable from a dividend. The Supreme Court observed that the transaction in *Gregory* was "an operation having no business or corporate purpose–a mere device which put on the form of a corporate reorganization as a disguise for concealing its real character." *Gregory,* 293 U.S. at 469.

Other courts have found that a transaction does qualify under section 355 despite its failure to comply with all of the statutory requirements. For example, in *Commissioner* v. *Gordon,* 382 F.2d 499 (2d Cir.1967), *rev'd on other grounds,* 391 U.S. 83 (1968), the court addressed section 355(b)(2)(C). Pursuant to that section, a corporation is treated as engaged in the active conduct of a trade or business only if the trade or business was not acquired in a transaction in which gain or loss was recognized in whole or in part within the five-year period ending on the date of the distribution. The court concluded that, despite the fact that gain was recognized when Distributing transferred a trade or business to Controlled, section 355(b)(2)(C) was not violated because new assets were not brought within the combined corporate shells of Distributing and Controlled. The court stated:

> We think that the draftsmen of Section 355 intended these subsections to apply only to the bringing of new assets within the combined corporate shells of the distributing and the controlled corporations. Therefore, it is irrelevant in this case whether gain was recognized on the intercorporate transfer.

Id. at 507.

3. Device Regulations

a. 1955 Regulations

Regulations under section 355 of the 1954 Code were issued in 1955 (the 1955 regulations). TD 6152 (20 FR 8875). These regulations included § 1.355–2(b)(3), which provided the following:

> In determining whether a transaction was used principally as a device for the distribution of the earnings and profits of the distributing corporation or of the controlled corporation or both, consideration will be given to all of the facts and circumstances of the transaction. In particular, consideration will be given to the nature, kind and amount of the assets of both corporations (and corporations controlled by them) immediately after the transaction. The fact that at the time of the transaction substantially all of the assets of each of the corporations involved are and have been used in the active conduct of trades or businesses which meet the requirements of section 355(b) will be considered evidence that the transaction was not used principally as such a device.

b. 1989 Regulations

Additional regulations under section 355 were issued in 1989 (the 1989 regulations). TD 8238 (54 FR 283). These regulations provide substantially more guidance than the 1955 regulations to determine whether a distribution was a device. Section 1.355–2(d)(1) provides that "a tax-free distribution of the stock of a controlled corporation presents a potential for tax avoidance by facilitating the avoidance of the dividend provisions of the Code through the subsequent sale or exchange of stock of one corporation and the retention of the stock of another corporation. A device can include a transaction that effects a recovery of basis."

This provision clarifies that, although the device prohibition primarily targets the conversion of dividend income to capital gain, a device can still exist if there would be a recovery of stock basis in lieu of receipt of dividend income and even if the shareholder's federal income tax rates on dividend income and capital gain are the same.

The 1989 regulations also expand on the statement in the 1955 regulations that the device analysis takes into account all of the facts and circumstances by specifying three factors that are evidence of device and three factors that are evidence of nondevice. One of the device factors, described in § 1.355–2(d)(2)(iv)(B), expands the statement in the 1955 regulations that consideration will be given to the nature, kind, and amount of the assets of Distributing and Controlled immediately after the transaction (the nature and use of assets device factor). First, this provision provides that "[t]he existence of assets that are not used in a trade or business that satisfies the requirements of section 355(b) is evidence of device. For this purpose, assets that are not used in a trade or business that satisfies the requirements of section 355(b) include, but are not limited to, cash and other liquid assets that are not related to the reasonable needs of a business satisfying such section." This provision continues to provide that "[t]he strength of the evidence of device depends on all the facts and circumstances, including, but not limited to, the ratio for each corporation of the value of assets not used in a trade or business that satisfies the requirements of section 355(b) to the value of its business that satisfies such requirements." Finally, the provision provides that "[a] difference in the ratio described in the preceding sentence for the distributing and controlled corporation is ordinarily not evidence of device if the distribution is not pro rata among the shareholders of the distributing corporation and such difference is attributable to a need to equalize the value of the stock distributed and the value of the stock or securities exchanged by the distributees."

Although this provision describes the factor, it provides little guidance relating to the quality or quantity of the relevant assets and no guidance on how the factor relates to other device factors or nondevice factors.

The nondevice factors in § 1.355–2(d)(3) are the presence of a corporate business purpose, the fact that the stock of Distributing is publicly traded and widely held, and the fact that the distribution is made to certain domestic corporate shareholders.

Section 1.355–2(d)(5) specifies certain distributions that ordinarily are not considered a device, notwithstanding the presence of device factors, because they ordinarily do not present the potential for federal income tax avoidance in converting dividend income to capital gain or using stock basis to reduce shareholder-level tax. These transactions include a distribution that, in the absence of section 355, with respect to each distributee, would be a redemption to which sale-or-exchange treatment applies.

4. Active Business Requirement Regulations

Section 1.355–3 provides rules for determining whether Distributing and Controlled satisfy the active business requirement. Proposed regulations issued in 2007 would amend § 1.355–3. REG–123365–03 (72 FR 26012). The Treasury Department and the IRS continue to study the active business requirement issues considered in those proposed regulations.

5. Administration of the Active Business Requirement

The fact that Distributing's or Controlled's qualifying active business is small in relation to all the assets of Distributing or Controlled is generally recognized as a device factor. A separate issue is whether a relatively small active business satisfies the active business requirement. In Rev. Rul. 73–44 (1973–1 CB 182), Controlled's active business represented a "substantial portion" but less than half of the value of its total assets. The revenue ruling states:

> There is no requirement in section 355(b) that a specific percentage of the corporation's assets be devoted to the active conduct of a trade or business. In the instant case, therefore, it is not controlling for purposes of the active business requirement that the active business assets of the controlled corporation, Y, represent less than half of the value of the controlled corporation immediately after the distribution.

The IRS has taken the position, in letter rulings and internal memoranda, that an active business can satisfy the active business requirement regardless of its absolute or relative size. However, no published guidance issued by the Treasury Department or the IRS takes this position.

In 1996, the Treasury Department and the IRS issued Rev. Proc. 96–43 (1996–2 CB 330), which provided that (1) the IRS ordinarily would not issue a letter ruling or determination letter on whether a distribution was described in section 355(a)(1) if the gross assets of the active business would have a fair market value that was less than five percent of the total fair market value of the gross assets of the corporation directly conducting the active business, but (2) a ruling might be issued "if it can be established that, based upon all relevant facts and circumstances, the trades or businesses are not de minimis compared with the other assets or activities of the corporation and its subsidiaries." This no-rule provision was eliminated in Rev. Proc. 2003–48 (2003–2 CB 86). Since that time, until the publication of Rev. Proc. 2015–43 (2015–40 IRB 467) and Notice 2015–59 (2015–40 IRB 459), discussed in Part D.1 of this Background section of the preamble, the IRS maintained its position that the relative size of an active business is a device factor rather than a section 355(b) requirement. The IRS issued numerous letter rulings on section 355 distributions involving active businesses that were de minimis in value compared to the other assets of Distributing or Controlled.

The IRS interpreted section 355(b) in this manner in part as a result of the mechanical difficulties of satisfying the active business requirement. These mechanical difficulties are discussed further in Part D.3.c of this Background section of the preamble.

As an example, until section 355(b) was amended by section 202 of the Tax Increase Prevention and Reconciliation Act of 2005, Public Law 109–222 (120 Stat. 345, 348); Division A, section 410 of the Tax Relief and Health Care Act of 2006, Public Law 109–432 (120 Stat. 2922, 2963); and section 4(b) of the Tax Technical Corrections Act of 2007, Public Law 110–172 (121 Stat. 2473, 2476) (the Separate Affiliated Group, or SAG, Amendments), if, immediately after the distribution, a corporation did not directly engage in an active business, it could satisfy the active business requirement only if substantially all of its assets consisted of stock and securities of corporations it controlled that were engaged in an active business (the holding company rule). *See* section 355(b) prior to the SAG Amendments. Because of the limited application of the holding company rule, corporations often had to undergo burdensome restructurings prior to section 355 distributions merely to satisfy the active business requirement. *See, e.g.,* H.R. Rep. No. 109–304, at 54 (2005).

As another example, until 1992, no guidance provided that Distributing or Controlled could rely on activities conducted by a partnership to satisfy the active business requirement, even if Distributing or Controlled held a substantial interest in the partnership and participated in its management. This situation changed after the Treasury Department and the IRS published revenue rulings permitting this reliance. *See* Rev. Rul. 92–17 (1992–1 CB 142) *amplified by* Rev. Rul. 2002–49 (2002–2 CB 288) *and modified by* Rev. Rul. 2007–42 (2007–2 CB 44).

6. Administration of the Device Prohibition

The device prohibition continues to be important even though the federal income tax rates for dividend income and capital gain may be identical for many taxpayers. In Rev. Proc. 2003–48, the Treasury Department and the IRS announced that the IRS would no longer rule on whether a transaction is a device or has a business purpose. As a result, since the publication of Rev. Proc. 2003–48, the IRS has made only limited inquiries as to device and business purpose issues raised in requests for private letter rulings under section 355.

D. Reasons for Proposed Regulations

1. Rev. Proc. 2015–43 and Notice 2015–59

As explained in Part C of this Background section of the preamble, section 355 and its predecessors have had a long and contentious history. Despite the safeguards in the Code and regulations, and the courts' interpretations in accordance with congressionally-articulated statutory purposes, taxpayers have attempted to use section 355 distributions in ways that the Treasury Department and the IRS have determined to be inconsistent with the purpose of section 355.

On September 14, 2015, the Treasury Department and the IRS issued Rev. Proc. 2015–43 and Notice 2015–59 in response to concerns relating to distributions involving relatively small active businesses, substantial amounts of investment assets, and regulated investment companies (RICs) or real estate investment trusts (REITs). The notice states that the Treasury Department and the IRS are studying issues under sections 337(d) and 355 relating to these transactions and that these transactions may present evidence of device, lack an adequate business purpose or a qualifying active business, or circumvent the purposes of Code provisions intended to implement repeal of the *General Utilities* doctrine, a doctrine under which a corporation generally could distribute appreciated property to its shareholders without recognizing gain (*General Utilities* repeal). The notice invited comments with respect to these issues and one commenter (the commenter) submitted a comment letter.

The proposed regulations in this notice of proposed rulemaking would address the device prohibition (including the business purpose requirement as it pertains to device) and the active business requirement. Congress has addressed certain other issues discussed in Notice 2015–59. *See* section 311 of the Protecting Americans from Tax Hikes Act of 2015, Public Law 114–113 (129 Stat. 3040, 3090), in which Congress added section 355(h), which generally denies section 355 treatment if either Distributing or Controlled is a REIT unless both are REITs immediately after the distribution, and section 856(c)(8), which generally provides that Distributing or Controlled will not be eligible to make a REIT election within the ten-year period after a section 355 distribution. Separate temporary and proposed regulations address transactions that avoid the application of sections 355(h) and 856(c)(8). *See* REG–126452–15 (Certain Transfers of Property to RICs and REITs) (81 FR 36816), cross-referencing TD 9770 (81 FR 36793). The Treasury Department and the IRS continue to study issues relating to *General Utilities* repeal presented by other transactions involving the separation of nonbusiness assets from business assets, and are considering issuing guidance under section 337(d) to address these issues. *See* Part D.4 of this Background section of the preamble.

2. Comments Regarding Device

The commenter believes that new rules are not needed for transactions that raise the purely shareholder-level concerns that are the subject of the device prohibition. According to the commenter, those transactions likely do not qualify under section 355 under current law and are infrequent. Although largely agreeing with this statement, the Treasury Department and the IRS have determined that certain clarifying changes should be made to the device rules. As discussed in Part C.3.b of this Background section of the preamble, the current regulations relating to device are not specific as to the quality or quantity of assets relevant in the nature and use of assets device factor or the appropriate weighing of the device and nondevice factors. The Treasury Department and the IRS have determined that, in some situations, insufficient weight has been given to the nature and use of assets device factor and that device factors have not been balanced correctly against nondevice factors.

For example, if, after a distribution, Distributing or Controlled holds mostly liquid nonbusiness assets, the shareholders of that corporation can sell their stock at a price that reflects the value of the nonbusiness assets, and such a sale is economically similar to a distribution of the liquid nonbusiness assets to the shareholders that would have been treated as a dividend to the extent of earnings and profits of the corporation. *See, e.g., Gregory.* If Distributing's ratio of nonbusiness assets to total assets differs substantially from Controlled's ratio, the distribution could facilitate a separation of the nonbusiness assets from the business assets by means of the sale of the stock in the corporation with a large percentage of nonbusiness assets. No corporate-level gain, and possibly little or no shareholder-level gain, would be recognized.

Taxpayers have taken the position that nondevice factors in the regulations can outweigh the substantial evidence of device presented in such distributions. For example, certain taxpayers have viewed even a weak business purpose, combined with the fact that the stock of Distributing is publicly traded, as offsetting evidence of device presented by distributions effecting a separation of nonbusiness assets from business assets, even if pressure from public shareholders was a significant motivation for the distribution. The Treasury Department and the IRS do not agree that these types of nondevice factors should outweigh the substantial evidence of device presented by a distribution that separates nonbusiness assets from business assets.

Accordingly, the Treasury Department and the IRS have determined that the regulations should provide clearer, more objective guidance regarding the nature and use of assets device factor and the appropriate weighing of device factors and nondevice factors. The Treasury Department and the IRS also have determined that if a high enough proportion of assets of Distributing or Controlled consists of nonbusiness assets, and if the assets of the other corporation include a much lower proportion of nonbusiness assets, the evidence of device is so strong that nondevice factors generally should not be allowed to overcome the evidence of device.

The commenter also noted that the importance of device, traditionally understood as reflecting shareholder-level policies, has diminished in the context of a unified rate regime for long-term capital gains and qualified dividend income for some taxpayers. However, because of continuing differences in the federal income tax treatment of capital gains and dividends, including the potential for basis recovery (*see* § 1.355–2(d)(1)) and the availability of capital gains to absorb capital losses, the device prohibition continues to be important.

3. Comments Regarding Active Business

a. Section 355(b) Requires Minimum Size Active Business

The commenter stated that section 355 is meant to apply to genuine separations of businesses, and that section 355(b) should not function as a formality. Nevertheless, the commenter does not believe that the active business requirement needs to be strengthened through the adoption of a requirement of a minimum amount of active business assets.

After studying this issue, the Treasury Department and the IRS have determined that Distributing or Controlled should not satisfy the active business requirement by holding a relatively de minimis active business. As described in the remainder of this Part D.3, the Treasury Department and the IRS have determined that interpreting section 355(b) as having meaning and substance and therefore requiring an active business that is economically significant is consistent with congressional intent, case law, and the reorganization provisions. In addition, given the developments in the tax law described in Part D.3.c of this Background section of the preamble, the Treasury Department and the IRS have determined that allowing a de minimis active business to satisfy the active business requirement is not necessary to reduce the burden of compliance with the active business requirement. Furthermore, requiring a minimum relative size for an active business is not inconsistent with the facts of Rev. Rul. 73–44 or with its conclusion. *See* Part D.3.d of this Background section of the preamble.

b. Consistent With Congressional Intent, Case Law, and the Reorganization Provisions

Allowing section 355(b) to be satisfied with an active business that is economically insignificant in relation to other assets of Distributing or Controlled is not consistent with the congressional purpose for adopting the active business requirement. It is generally understood that Congress intended section 355 to be used to separate businesses, not to separate inactive assets from a business. *See* S. Rep. No. 83–1622, at 50–51 (section 355 "contemplates that a tax-free separation shall involve only the separation of assets attributable to the carrying on of an active business" and does not permit "the tax free separation of an existing corporation into active and inactive entities"); *see also Coady* v. *Commissioner,* 33 T.C. 771, 777 (1960), *aff'd,* 289 F.2d 490 (6th Cir. 1961) (stating that a function of section 355(b) is "to prevent the tax-free separation of *active* and *inactive* assets into *active* and *inactive* corporate entities") (emphasis in original); § 1.355–1(b) ("[s]ection 355 provides for the separation . . . of one or more existing businesses"). Additionally, when the active business of Distributing or Controlled is economically insignificant in relation to its other assets, it is unlikely that any non-federal tax purpose for separating that business from other businesses is a significant purpose for the distribution. *See* § 1.355–2(b)(1) ("Section 355 applies to a transaction only if it is carried out for one or more corporate business purposes. . . . The potential for the avoidance of Federal taxes by the distributing or controlled corporations . . . is relevant in determining the extent to which an existing corporate business purpose motivated the distribution.").

Further, as the Supreme Court held in *Gregory,* transactions are to be taxed in accordance with their substance. The reorganization regulations adopt the same principle. For example, § 1.368–1(b) provides that "[b]oth the terms of the specifications [of the reorganization provisions] and their underlying assumptions and purposes must be satisfied in order to entitle the taxpayer to the benefit of the exception from the general rule." Additionally, § 1.368–1(c) provides that "[a] scheme, which involves an abrupt departure from normal reorganization procedure in connection with a transaction on which the imposition of tax is imminent, such as a mere device that puts on the form of a corporate reorganization as a disguise for concealing its real character, and the object and accomplishment of which is the consummation of a preconceived plan having no business or corporate purpose, is not a plan of reorganization."

Accordingly, when a corporation that owns only nonbusiness assets and a relatively de minimis active business is separated from a corporation with another active business, the substance of the transaction is not a separation of businesses as contemplated by section 355.

c. Developments in the Tax Law Reduce the Burden of Complying With Section 355

In the past, the active business requirement was more difficult to satisfy than it is today, in part because of the limited application of the holding company rule, discussed in Part C.5 of this Background section of the preamble. However, several developments in the tax law have occurred that make the active business requirement easier to satisfy and negate the historical need to reduce the administrative burden of complying with section 355(b).

In the SAG Amendments, Congress amended section 355(b) to adopt the separate affiliated group rules of section 355(b)(3). Section 355(b)(3)(A) provides that, for purposes of determining whether a corporation meets the requirements of section 355(b)(2)(A), all members of the corporation's separate affiliated group (SAG) are treated as one corporation. Section 355(b)(3)(B) provides that a corporation's SAG is the affiliated group which would be determined under section 1504(a) if the corporation were the common parent and section 1504(b) did not apply.

Additionally, as discussed in Part C.5 of this Background section of the preamble, section 355(b) now can be satisfied through the ownership of certain interests in a partnership that is engaged in an active business. *See* Rev. Rul. 2007–42 and Rev. Rul. 92–17. Similarly, § 301.7701–3 now allows an eligible entity to elect to be disregarded as an entity separate from its owner and permits a corporation to satisfy the active business requirement through a tax-free acquisition without having to assume liabilities relating to an active business. Finally, the expansion rules of § 1.355–3(b)(3)(ii) have been developed so that it is easier to acquire the assets of an active business in a taxable transaction while complying with section 355(b). *See, e.g.,* Rev. Rul. 2003–18 (2003–1 CB 467) and Rev. Rul. 2003–38 (2003–1 CB 811) (both describing facts and circumstances to be considered in determining whether one trade or business is in the same line of business as another).

d. Rev. Rul. 73–44

Rev. Rul. 73–44 is sometimes cited in support of the proposition that a de minimis active business satisfies the section 355(b) requirement. However, Rev. Rul. 73–44 states only that there is no requirement in section 355(b) that a specific percentage of a corporation's assets be devoted to the active conduct of a trade or business, not that any size active business can satisfy section 355(b). In fact, the size of the active business in that ruling represented a substantial portion of Controlled's assets, although less than half of Controlled's value. Accordingly, Rev. Rul. 73–44 does not validate a section 355 distribution involving a de minimis active business, and the proposed regulations in this notice of proposed rulemaking addressing the minimum relative size of active businesses would not change the conclusion set forth in that revenue ruling. Nevertheless, the Treasury Department and the IRS intend to modify Rev. Rul. 73–44 with regard to the statement in the revenue ruling that there is no requirement that a specific percentage of a corporation's assets be devoted to the active conduct of a trade or business.

4. General Utilities Repeal

The Treasury Department and the IRS have observed, as noted in Notice 2015–59, that taxpayers may attempt to use section 355 distributions in ways that are inconsistent with the purpose of *General Utilities* repeal. Specifically, the Treasury Department and the IRS are concerned that certain taxpayers may be interpreting the current regulations under sections 337(d) and 355 in a manner allowing tax-free distributions motivated in whole or substantial part by a purpose of avoiding corporate-level taxation of built-in gain in investment or nonbusiness assets. *See* § 1.355–1(b) ("Section 355 provides for the separation . . . of one or more existing businesses formerly operated, directly or indirectly, by a single corporation . . . ."). The Treasury Department and the IRS continue to study whether permitting tax-free separations of large amounts of nonbusiness assets from business assets, especially when the gain in the nonbusiness assets is expected to be eliminated, is consistent with *General Utilities* repeal in all circumstances. Comments are welcome on potential additional guidance under section 337(d) addressing such transactions.

Explanation of Provisions

A. Modification of Device Regulations

The proposed regulations would modify § 1.355–2(d), which addresses transactions that are or are not a device. The proposed regulations would modify the nature and use of assets device factor in § 1.355–2(d)(2)(iv), modify the corporate business purpose nondevice factor in § 1.355–2(d)(3)(ii), and add a per se device test.

1. Nature and Use of Assets

The Treasury Department and the IRS have determined that device potential generally exists either if Distributing or Controlled owns a large percentage of assets not used in business operations compared to total assets or if Distributing's and Controlled's percentages of these assets differs substantially. A proposed change to the nature and use of assets device factor in § 1.355–2(d)(2)(iv) would focus on assets used in a Business (Business Assets) (each as defined in proposed § 1.355–2(d)(2)(iv)(B)) rather than assets used in an active business meeting the requirements of section 355(b) (a Five-Year-Active Business, as defined in proposed § 1.355–9(a)(2)). In general, Business would have the same meaning as a Five-Year-Active Business, but without regard to whether the business has been operated or owned for at least five years prior to the date of the distribution or whether the collection of income requirement in § 1.355–3(b)(2)(ii) is satisfied. Business Assets would be gross assets used in a Business, including reasonable amounts of cash and cash equivalents held for working capital and assets required to be held to provide for exigencies related to a Business or for regulatory purposes with respect to a Business. The Treasury Department and the IRS have determined that the presence of

Business Assets generally does not raise any more device concerns than the presence of assets used in a Five-Year-Active Business (Five-Year-Active-Business Assets). Thus, the proposed regulations would modify § 1.355–2(d)(2)(iv)(B) to take into account Business Assets, not just Five-Year-Active-Business Assets.

Rev. Proc. 2015–43 (now incorporated into Rev. Proc. 2016–3 (2016–1 IRB 126)) and Notice 2015–59 focus on investment assets (using a modified section 355(g) definition) of a corporation as assets that may raise device concerns. However, after further study, the Treasury Department and the IRS have determined that investment assets as defined therein may include certain assets that do not raise device concerns, such as cash needed by a corporation for working capital, and may not include other assets that do raise device concerns, such as real estate not related to the taxpayer's Business. The Treasury Department and the IRS have determined that focusing on Nonbusiness Assets, as defined in the proposed regulations, is a better method of evaluating device or nondevice as compared to using investment assets as described in Rev. Proc. 2016–3 and Notice 2015–59. Thus, the proposed regulations would focus on Nonbusiness Assets rather than investment assets.

The proposed regulations would provide thresholds for determining whether the ownership of Nonbusiness Assets (gross assets that are not Business Assets) and/or differences in the Nonbusiness Asset Percentages (the percentage of a corporation's Total Assets (its Business Assets and Nonbusiness Assets) that are Nonbusiness Assets) for Distributing and Controlled are evidence of device. If neither Distributing nor Controlled has Nonbusiness Assets that comprise 20 percent or more of its Total Assets, the ownership of Nonbusiness Assets ordinarily would not be evidence of device. Additionally, a difference in the Nonbusiness Asset Percentages for Distributing and Controlled ordinarily would not be evidence of device if such difference is less than 10 percentage points or, in the case of a non-pro rata distribution, if the difference is attributable to a need to equalize the value of the Controlled stock and securities distributed and the consideration exchanged therefor by the distributees. Accordingly, the Treasury Department and the IRS propose to treat such circumstances as ordinarily not constituting evidence of device.

2. Corporate Business Purpose

The Treasury Department and the IRS also propose to revise the nondevice factor in § 1.355–2(d)(3)(ii), which relates to corporate business purpose for a transaction as evidence of nondevice. Under the proposed revision, a corporate business purpose that relates to a separation of Nonbusiness Assets from one or more Businesses or from Business Assets would not be evidence of nondevice, unless the business purpose involves an exigency that requires an investment or other use of the Nonbusiness Assets in a Business. The Treasury Department and the IRS have determined that, absent such an exigency, such separations are not consistent with the intent of Congress to prevent section 355 from applying to a distribution that is used principally as a device.

3. Per se Device Test

The Treasury Department and the IRS also propose to add a per se device test to the device determination in proposed § 1.355–2(d)(5). Under proposed § 1.355–2(d)(5), if designated percentages of Distributing's and/or Controlled's Total Assets are Nonbusiness Assets, the transaction would be considered a device, notwithstanding the presence of any other nondevice factors, for example, a corporate business purpose or stock being publicly traded and widely held. By their nature, these transactions present such clear evidence of device that the Treasury Department and the IRS have determined that the nondevice factors can never overcome the device potential. The only exceptions to this per se device rule would apply if the distribution is also described in § 1.355–2(d)(3)(iv) (distributions in which the corporate distributee would be entitled to a dividends received deduction under section 243(a) or 245(b)) or in redesignated § 1.355–2(d)(6) (§ 1.355–2(d)(5) of the current regulations, relating to transactions ordinarily not considered as a device).

The per se device test would have two prongs, both of which must be met for the distribution to be treated as a per se device.

The first prong would be if Distributing or Controlled has a Nonbusiness Asset Percentage of 66⅔ percent or more. If 66⅔ percent or more of the Total Assets of either corporation consist of Nonbusiness Assets, a strong device potential exists.

The second prong of the test would compare the Nonbusiness Asset Percentage of Distributing with that of Controlled. The comparison would be similar to the comparison, in § 1.355–2(d)(2)(iv)(B) of the current regulations, between Distributing's ratio of assets not used in a Five-Year-Active Business to assets used in a Five-Year-Active Business and Controlled's ratio of such assets. However, the Treasury Department and the IRS recognize that valuation of assets may be difficult and that determining whether certain assets are Business Assets also may be difficult. Accordingly, rather than requiring Distributing and Controlled to make exact determinations of their Nonbusiness Asset Percentages, which would then be compared to the other corporation's Nonbusiness Asset Percentage, the second prong of the per se device test would provide for three bands in making this comparison. These bands generally would provide for the comparison of the Nonbusiness Asset Percentages of Distributing and Controlled but require less precision in asset valuation.

In the first band, if one corporation's Nonbusiness Asset Percentage is 66⅔ percent or more, but less than 80 percent, the distribution would fall within the band if the other corporation's Nonbusiness Asset Percentage is less than 30 percent. In the second band, if one corporation's Nonbusiness Asset Percentage is 80 percent or more, but less than 90 percent, the distribution would fall within the band if the other corporation's Nonbusiness Asset Percentage is less than 40 percent. In the third band, if one corporation's Nonbusiness Asset Percentage is 90 percent or more, the distribution would fall within the band if the other corporation's Nonbusiness Asset Percentage is less than 50 percent. All of these bands represent cases in which the Nonbusiness Asset Percentages of Distributing and Controlled are significantly different.

If both prongs of the per se device test are met, that is, if the Nonbusiness Asset Percentage for either Distributing or Controlled is 66⅔ percent or more and the Nonbusiness Asset Percentages of Distributing and Controlled fall within one of the three bands, the distribution would be a per se device. Otherwise, the general facts-and-circumstances test of § 1.355–2(d), as modified by these proposed regulations, would apply to determine if the transaction was a device.

4. Certain Operating Rules

In making the determination of which assets of a corporation are Business Assets and which are Nonbusiness Assets, if Distributing or Controlled owns a partnership interest or stock in another corporation, the proposed regulations would provide four operating rules.

First, all members of a SAG with respect to which Controlled is the common parent (CSAG) and all members of a SAG with respect to which Distributing is the common parent excluding Controlled and its SAG (DSAG) would be treated as a single corporation. Thus, any stock owned by one member of a SAG in another member of the same SAG and any intercompany obligations between the same SAG members would be disregarded.

Second, a partnership interest would generally be considered a Nonbusiness Asset. However, if, by reason of a corporation's ownership interest or its ownership interest and participation in management of the partnership, the corporation is considered to be engaged in the Business conducted by such partnership (based on the criteria that would be used to determine whether such corporation is considered to be engaged in the Five-Year-Active Business of such partnership under Rev. Ruls. 92–17, 2002–49, and 2007–42), the fair market value of the partnership interest would be allocated between Business Assets and Nonbusiness Assets in the same proportion as the proportion of the fair market values of the Business Assets and the Nonbusiness Assets of the partnership.

Third, a rule similar to the partnership interest rule would apply for corporate stock owned by Distributing or Controlled. That is, stock in a corporation, other than a member of the DSAG or the CSAG, would generally be a Nonbusiness Asset. However, there would be an exception for stock in a Member of a 50-Percent-Owned Group. For this purpose, a 50-Percent-Owned Group would have the same meaning as SAG, except substituting "50-percent" for "80-percent," and a Member of a 50-Percent-Owned Group would be a corporation that would be a member of a DSAG or CSAG, with such substitution. If a Member of a 50-Percent-Owned Group with respect to Distributing or Controlled owns stock in another Member of such 50-Percent-Owned Group (other than a member of the DSAG or the CSAG, respectively), the fair market value of such stock would be allocated between Business Assets and Nonbusiness Assets in the same proportion as the proportion of the fair market values of the Business Assets and the Nonbusiness Assets of the issuing corporation.

Fourth, the proposed regulations would provide for adjustments to prevent distortion if Distributing or Controlled owes money to or is owed money by a partnership or Member of a 50-Percent-Owned Group.

The partnership rules and the 50-Percent-Owned Group rules are designed to recognize that ownership of a partnership interest or stock in a Member of a 50-Percent-Owned Group may reflect an investment in Business Assets, Nonbusiness Assets, or both, while minimizing the significance of changes in the form of ownership of Business Assets and Nonbusiness Assets.

5. Multiple Controlleds

If a transaction involves distributions by Distributing of the stock of more than one Controlled, proposed §§ 1.355–2(d)(2)(iv) and 1.355–2(d)(5) would apply to all such Controlleds. To the extent any rule would require a comparison between characteristics of Distributing and Controlled, there would have to be a comparison between Distributing and each Controlled and between each Controlled and each other Controlled. If any comparison under proposed § 1.355–2(d)(2)(iv) or § 1.355–2(d)(5) would result in a determination that a distribution is a device, then all distributions involved in the transaction would be considered a device.

B. Minimum Size for Active Business

Section 355(b) does not literally provide a minimum absolute or relative size requirement for an active business to qualify under section 355(b). Nevertheless, as discussed in Part D.3 of the Background section of the preamble, the Treasury Department and the IRS have determined that Congress intended that section 355(b) would require that distributions have substance and that a distribution involving only a relatively de minimis active business should not qualify under section 355 because such a distribution is not a separation of businesses as contemplated by section 355.

To ensure that congressional intent is satisfied and to reduce uncertainty, the Treasury Department and the IRS propose to add new § 1.355–9. This section would provide that, for the requirements of section 355(a)(1)(C) and (b) to be satisfied with respect to a distribution, the Five-Year-Active-Business Asset Percentage (the percentage determined by dividing the fair market value of a corporation's Five-Year-Active-Business Assets by the fair market value of its Total Assets) of each of Controlled (or the CSAG) and Distributing (or the DSAG excluding Controlled and other CSAG members) must be at least five percent. Similar to the proposed definition of Business Assets, Five-Year-Active-Business Assets would include reasonable amounts of cash and cash equivalents held for working capital and assets required to be held to provide for exigencies related to a Five-Year-Active Business or for regulatory purposes with respect to a Five-Year-Active Business.

In making the determination of the percentage of a corporation's assets that are Five-Year-Active-Business Assets, if a corporation is considered to be engaged in a Five-Year-Active Business of a partnership, the fair market value of the partnership interest would be allocated between Five-Year-Active-Business Assets and Non-Five-Year-Active-Business Assets (assets other than Five-Year-Active-Business Assets) in the same proportion as the proportion of the fair market values of Five-Year-Active-Business Assets and Non-Five-Year-Active-Business Assets of the partnership.

Except in the case of a member of its SAG, neither Distributing nor Controlled would be considered to be engaged in the Five-Year-Active Business of a corporation in which it owns stock. Accordingly, such stock in a corporation would be considered a Non-Five-Year-Active-Business Asset. Although the proposed regulations relating to the device prohibition would provide an allocation rule for assets held by a Member of a 50-Percent-Owned Group, discussed in Part A.4 of this Explanation of Provisions section of the preamble, the Treasury Department and the IRS believe the SAG Amendments, discussed in Parts C.5 and D.3.c of the Background section of the preamble, limit the ability to take into account assets held by subsidiaries for purposes of the active business requirement. Accordingly, proposed § 1.355–9 would not provide a similar allocation rule for stock owned by Distributing or Controlled.

The commenter stated that the regulations should not provide a minimum size requirement for an active business in any distribution and that such a requirement could be especially problematic in intra-group distributions in preparation for a distribution outside of a group. Internal distributions often are necessary to align the proper assets within Distributing and Controlled prior to a distribution of the stock of Controlled outside the group. If a minimum size requirement is imposed on each of these internal distributions, taxpayers may have to undertake movements of active businesses within groups to meet the minimum size requirement for each internal distribution.

In enacting the SAG Amendments, Congress did not provide an exception to the requirements of section 355(b) for internal distributions that are preparatory to external distributions, although Congress permitted Distributing and Controlled to rely on active businesses held by members of their respective SAGs, even if such assets were distributed or sold within the SAG in a taxable transaction. Under the commenter's rationale, the regulations should not only permit an internal distribution with a de minimis active business, but could also permit tax-free treatment for taxable distributions or sales of assets within the SAG if such assets need to be moved in preparation of the external distribution. The Treasury Department and the IRS have determined that each distribution must meet all the requirements of section 355, including the requirement that Distributing and each Controlled conduct an active business immediately after the distribution. Accordingly, the proposed regulations would provide a five-percent minimum Five-Year-Active-Business Asset Percentage requirement for all distributions.

C. Timing of Asset Identification, Characterization, and Valuation

For purposes of determining whether a transaction would be considered a device and whether one or more Five-Year-Active Businesses would meet the five-percent minimum Five-Year-Active-Business Asset Percentage requirement of proposed § 1.355–9, the assets held by Distributing and by Controlled must be identified, and their character and fair market value must be determined. The assets under consideration would be the assets held by Distributing and by Controlled immediately after the distribution. Thus, for example, the stock of Controlled that is distributed would not be an asset of Distributing for this purpose. The character of the assets held by Distributing and by Controlled, as Business Assets or Nonbusiness Assets or as Five-Year-Active-Business Assets or Non-Five-Year-Active-Business Assets, also would be the character as determined immediately after the distribution.

The proposed regulations would provide, however, that the fair market value of assets would be determined, at the election of the parties on a consistent basis, either (a) immediately before the distribution, (b) on any date within the 60-day period before the distribution, (c) on the date of an agreement with respect to the distribution that was binding on Distributing on such date and at all times thereafter, or (d) on the date of a public announcement or filing with the Securities and Exchange Commission with respect to the distribution. The parties would be required to make consistent determinations between themselves, and use the same date, for purposes of applying the device rules of proposed § 1.355–2(d) and the five-percent minimum Five-Year-Active-Business Asset Percentage requirement of proposed § 1.355–9. If the parties do not meet these consistency requirements, the valuation would be determined as of immediately before the distribution unless the Commissioner determines that the use of such date is inconsistent with the purposes of section 355 and the regulations thereunder.

D. Anti-Abuse Rules

The proposed regulations would also provide anti-abuse rules. Under the anti-abuse rules, a transaction or series of transactions (such as a change in the form of ownership of an asset; an issuance, assumption or repayment of indebtedness; or an issuance or redemption of stock) would not be given effect if undertaken with a principal purpose of affecting the Nonbusiness Asset Percentage of any corporation in order to avoid a determination that a distribution was a device or affecting the Five-Year-Active-Business Asset Percentage of any corporation in order to avoid a determination that a distribution does not meet the requirements of § 1.355–9. The transactions covered by the anti-abuse rules generally would not include an acquisition or disposition of assets, other than an acquisition from or disposition to a person the ownership of whose stock would, under section 318(a) (other than paragraph (4) thereof), be attributed to Distributing or Controlled, or a transfer of assets between Distributing and Controlled. However, such transactions would not be given effect if they are transitory, for example, if Distributing contributes cash to Controlled and retains some of the stock of Controlled or Controlled debt instruments, and there is a plan or intention for Controlled to return the cash to Distributing in redemption of the stock or repayment of the debt.

Statement of Availability of IRS Documents

IRS revenue procedures, revenue rulings, notices, and other guidance cited in this document are published in the Internal Revenue Bulletin (or Cumulative Bulletin) and are available from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402, or by visiting the IRS Web site at *http://www.irs.gov.*

Effect on Other Documents

Section 3 of Notice 2015–59 is obsolete as of July 15, 2016. The IRS will modify Rev. Rul. 73–44, as of the date the Treasury decision adopting these regulations as final regulations is published in the **Federal Register**, as necessary to conform to § 1.355–9 of these proposed regulations. The IRS solicits comments as to whether other publications should be modified, clarified, or obsoleted.

Special Analyses

Certain IRS regulations, including this one, are exempt from the requirements of Executive Order 12866, as supplemented and reaffirmed by Executive Order 13563. Therefore, a regulatory impact assessment is not required. It has also been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these proposed regulations. Pursuant to the Regulatory Flexibility Act (5 U.S.C. chapter 6), it is hereby certified that this regulation will not have a significant economic impact on a substantial number of small entities. This certification is based on the fact that these regulations primarily affect larger corporations operating more than one business and with a substantial number of shareholders. Thus, these regulations are not expected to affect a substantial number of small entities. Accordingly, a regulatory flexibility analysis is not required. Pursuant to section 7805(f) of the Code, these regulations will be submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small business.

Comments and Requests for Public Hearing

Before these proposed regulations are adopted as final regulations, consideration will be given to any written or electronic comments that are submitted timely to the IRS as prescribed in this preamble under the **ADDRESSES** heading. The Treasury Department and the IRS request comments on all aspects of the proposed regulations, including—

1. Whether there should be any exceptions to the application of proposed § 1.355–9.
2. Whether additional exceptions should be incorporated into the per se device rule in proposed § 1.355–2(d)(5).
3. The scope of the safe harbors relating to presence of Nonbusiness Assets as evidence of device under

proposed § 1.355–2(d)(2)(iv)(C)(*1*) and (*2*) and whether additional safe harbors should be added to proposed § 1.355–2(d).

4. Whether the definition of Business Assets in proposed § 1.355–2(d)(2)(iv)(B)(*2*) should be revised, for example, to include additional categories of assets or to include cash or cash equivalents expected to be used for other categories of expenditures.

5. Whether the operating rules applicable to proposed § 1.355–2(d)(2)(iv)(D)(*6*) through (*8*) concerning the allocation of the value of a partnership interest between Business Assets and Nonbusiness Assets to its partners, the allocation of the value of the stock of a Member of a 50-Percent-Owned Group between Business Assets and Nonbusiness Assets to its shareholders, and certain borrowings should be modified, including whether the partnership rule should allocate an allocable share of the partnership's gross assets to its partners, whether different allocation rules should be used for partnership interests with different characteristics(for example, limited liability vs. non-limited liability), and whether the rules relating to borrowing between a partnership and a partner or between a Member of a 50-Percent-Owned Group and a shareholder should be made more specific.

6. Whether the anti-abuse rules in the proposed regulations pertaining to device and the five-percent minimum Five-Year-Active-Business Assets requirement should be revised, for example, to include or exclude additional transactions or to include a reference to acquisitions of assets by Distributing or Controlled on behalf of shareholders.

7. Whether the absence of any device factor, for example, a small difference in Nonbusiness Asset Percentages for Distributing and Controlled, should be considered a nondevice factor.

All comments will be available at *www.regulations.gov* or upon request.

A public hearing will be scheduled if requested in writing by any person that timely submits written or electronic comments. If a public hearing is scheduled, notice of the date, time, and place for the public hearing will be published in the **Federal Register**.

Drafting Information

The principal authors of these proposed regulations are Stephanie D. Floyd and Russell P. Subin of the Office of Associate Chief Counsel (Corporate). Other personnel from the Treasury Department and the IRS participated in their development.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Proposed Amendments to the Regulations

Accordingly, 26 CFR part 1 is proposed to be amended as follows:

PART 1—INCOME TAXES

■ **Paragraph 1.** The authority citation for part 1 continues to read in part as follows:

Authority: 6 U.S.C. 7805 * * *

■ **Par. 2.** Section 1.355–0 is amended by:

■ 1. Removing from the introductory text “1.355–7” and adding “1.355–9” in its place.

■ 2. Revising the entry for § 1.355–2(d)(2)(iv)(B).

■ 3. Adding entries for § 1.355–2(d)(2)(iv)(B)(*1*), (*2*), (*3*), (*4*), (*5*), (*6*), and (*7*).

■ 4. Redesignating the entry for § 1.355–2(d)(2)(iv)(C) as the entry for § 1.355–2(d)(2)(iv)(F).

■ 5. Adding a new entry for § 1.355–2(d)(2)(iv)(C).

■ 6. Adding entries for § 1.355–2(d)(2)(iv)(C)(*1*), (*2*), and (*3*).

■ 7. Adding an entry for § 1.355–2(d)(2)(iv)(D).

■ 8. Adding entries for § 1.355–2(d)(2)(iv)(D)(*1*), (*2*), (*3*), and (*4*).

■ 9. Adding entries for § 1.355–2(d)(2)(iv)(D)(*4*)(*i*) and (*ii*).

■ 10. Adding entries for § 1.355–2(d)(2)(iv)(D)(*5*) and (*6*).

■ 11. Adding entries for § 1.355–2(d)(2)(iv)(D)(*6*)(*i*) and (*ii*).

■ 12. Adding an entry for § 1.355–2(d)(2)(iv)(D)(*7*).

■ 13. Adding entries for § 1.355–2(d)(2)(iv)(D)(*7*)(*i*) and (*ii*).

■ 14. Adding an entry for § 1.355–2(d)(2)(iv)(D)(*8*).

■ 15. Adding an entry for § 1.355–2(d)(2)(iv)(E).

■ 16. Redesignating the entry for § 1.355–2(d)(5) as the entry for § 1.355–2(d)(6).

■ 17. Adding a new entry for § 1.355–2(d)(5).

■ 18. Adding entries for § 1.355–2(d)(5)(i), (ii), (iii), and (iv).

■ 19. Adding entries for § 1.355–2(i)(1), (i)(1)(i) and (ii), and (i)(2).

■ 20. Adding an entry for § 1.355–8.

■ 21. Adding entries for § 1.355–9.

The revisions and additions read as follows:

§ 1.355–0 Outline of sections.

* * * * *

§ 1.355–2 Limitations.

* * * * *

(d) * * *

(2) * * *

(iv) * * *

(B) Definitions.

(*1*) Business.

(*2*) Business Assets.

(*3*) Nonbusiness Assets.

(*4*) Total Assets.

(*5*) Nonbusiness Asset Percentage.

(*6*) Separate Affiliated Group, SAG, CSAG, and DSAG.

(*7*) 50-Percent-Owned Group, Member of a 50-Percent-Owned Group.

(C) Presence of Nonbusiness Assets as evidence of device.

(*1*) Ownership of Nonbusiness Assets.

(*2*) Difference between Nonbusiness Asset Percentages.

(*3*) Cross-reference.

(D) Operating rules.

(*1*) Multiple controlled corporations.

(*2*) Treatment of SAG as a single corporation.

(*3*) Time to identify assets and determine character of assets.

(*4*) Time to determine fair market value of assets.

(*i*) In general.

(*ii*) Consistency.

(*5*) Fair market value.

(*6*) Interest in partnership.

(*i*) In general.

(*ii*) Exception for certain interests in partnerships.

(*7*) Stock in corporation.

(*i*) In general.

(*ii*) Exception for stock in Member of a 50-Percent-Owned Group.

(*8*) Obligation between distributing corporation or controlled corporation and certain partnerships or Members of 50-Percent-Owned Groups.

(E) Anti-abuse rule.

* * * * *

(5) Distributions involving separation of Business Assets from Nonbusiness Assets.

(i) In general.

(ii) Definitions and operating rules.

(iii) Certain distributions involving separation of Nonbusiness Assets from Business Assets.

(iv) Anti-abuse rule.

* * * * *

(i) * * *

(1) Paragraph (d) of this section.

(i) In general.

(ii) Transition rule.

(2) Paragraph (g) of this section.

* * * * *

§ 1.355–8 Reserved.

§ 1.355–9 Minimum percentage of Five-Year-Active-Business Assets.

(a) Definitions.

(1) Distributing, Controlled.

(2) Five-Year-Active Business.

(3) Five-Year-Active-Business Assets.

(4) Non-Five-Year-Active-Business Assets.

(5) Total Assets.

(6) Five-Year-Active-Business Asset Percentage.

(7) Separate Affiliated Group, CSAG, and DSAG.

(b) Five percent minimum Five-Year-Active-Business Asset Percentage.

(c) Operating rules.

(1) Treatment of SAG and fair market value.

(2) Time to identify assets, determine character of assets, and determine fair market value of assets.

(3) Interest in partnership.

(i) In general.

(ii) Exception for certain interests in partnerships.

(d) Anti-abuse rule.

(e) Effective/applicability date.

(1) In general.

(2) Transition rule.

■ **Par. 3.** Section 1.355–2 is amended by:

■ 1. Adding the language "federal" before the language "tax avoidance" in the second sentence of paragraph (d)(1).

■ 2. Removing the last sentence of paragraph (d)(1) and adding two sentences at the end of the paragraph.

■ 3. Revising paragraphs (d)(2)(iv)(A) and (B).

■ 4. Redesignating paragraph (d)(2)(iv)(C) as (d)(2)(iv)(F).

■ 5. Adding new paragraphs (d)(2)(iv)(C), (D), and (E).

■ 6. Revising paragraph (d)(3)(ii).

■ 7. Removing from paragraph (d)(3)(ii)(A) the language "the business" and adding the language "one or more Businesses (as defined in paragraph (d)(2)(iv)(B)(*1*) of this section) of the distributing corporation, the controlled corporation, or both" in its place.

■ 8. Revising paragraph (d)(4).

■ 9. Redesignating paragraph (d)(5) as (d)(6).

■ 10. Adding a new paragraph (d)(5).

■ 11. Revising newly designated paragraph (d)(6)(i).

■ 12. Removing from newly designated paragraph (d)(6)(v) the language "subparagraph (5)" and adding the language "paragraph (d)(6)" in its place.

■ 13. Removing from the last sentence of newly designated paragraph (d)(6)(v) *Example 1* the language "(d)(5)(i)" and adding the language "(d)(6)(i)" in its place.

■ 14. Removing from the sixth sentence of newly designated paragraph (d)(6)(v) *Example 2* the language "(d)(5)(i)" and adding the language "(d)(6)(i)" in its place.

■ 15. Removing from the last sentence of newly designated paragraph (d)(6)(v) *Example 2* the language "made from all the facts" and adding the language "made from either the presence of a separation of Business Assets from Nonbusiness Assets as described in paragraph (d)(5) of this section or from all the facts" in its place.

■ 16. Adding to paragraph (h) the language "and § 1.355–9 (relating to Minimum Percentage of Five-Year-Active-Business Assets)" immediately before the language "are satisfied".

■ 17. Revising paragraph (i).

The revisions and additions read as follows:

§ 1.355–2 Limitations.

* * * * *

(d) * * *

(1) * * * However, if a transaction is specified in paragraph (d)(5)(iii) of this section, then it is considered to have been used principally as a device unless it is also specified in paragraph (d)(3)(iv) of this section or paragraph (d)(6) of this section. If a transaction is specified in paragraph (d)(6) of this section, then it is ordinarily considered not to have been used principally as a device.

(2) * * *

(iv) * * * (A) *In general.* The determination of whether a transaction was used principally as a device will take into account the nature, kind, amount, and use of the assets of the distributing corporation and the controlled corporation.

(B) *Definitions.* The following definitions apply for purposes of this paragraph (d)(2)(iv):

(*1*) *Business. Business* means the active conduct of a trade or business, within the meaning of section 355(b) and § 1.355–3, without regard to—

(*i*) The requirements of section 355(b)(2)(B), (C), and (D), and § 1.355–3(b)(3) and (4) (relating to active conduct throughout the five-year period preceding a distribution and acquisitions during such period);

(*ii*) The collection of income requirement in § 1.355–3(b)(2)(ii); and

(*iii*) The requirement of § 1.355–9 (relating to Minimum Percentage of Five-Year-Active-Business Assets (as defined in § 1.355–9(a)(3))).

(*2*) *Business Assets. Business Assets* of a corporation means its gross assets used in one or more Businesses. Such assets include cash and cash equivalents held as a reasonable amount of working capital for one or more Businesses. Such assets also include assets required (by binding commitment or legal requirement) to be held to provide for exigencies related to a Business or for regulatory purposes with respect to a Business. For this purpose, such assets include assets the holder is required (by binding commitment or legal requirement) to hold to secure or otherwise provide for a financial obligation reasonably expected to arise from a Business and assets held to implement a binding commitment to expend funds to expand or improve a Business.

(*3*) *Nonbusiness Assets. Nonbusiness Assets* of a corporation means its gross assets other than its Business Assets.

(*4*) *Total Assets. Total Assets* of a corporation means its Business Assets and its Nonbusiness Assets.

(*5*) *Nonbusiness Asset Percentage.* The *Nonbusiness Asset Percentage* of a corporation is the percentage determined by dividing the fair market value of its Nonbusiness Assets by the fair market value of its Total Assets.

(*6*) *Separate Affiliated Group, SAG, CSAG, and DSAG. Separate Affiliated Group* (or *SAG*) means a separate affiliated group as defined in section 355(b)(3)(B), *CSAG* means a SAG with respect to which a controlled corporation is the common parent, and *DSAG* means a SAG with respect to which a distributing corporation is the common parent, excluding the controlled corporation and any other members of the CSAG.

(*7*) *50-Percent-Owned Group, Member of a 50-Percent-Owned Group. 50-Percent-Owned Group* has the same meaning as SAG, except that "50-percent" is substituted for "80-percent" each place it appears in section 1504(a)(2), for purposes of section 355(b)(3)(B). A *Member of a 50-Percent-Owned Group* is a corporation that would be a member of a DSAG or a CSAG, with the substitution provided in this paragraph (d)(2)(iv)(B)(*7*).

(C) *Presence of Nonbusiness Assets as evidence of device*—(*1*) *Ownership of Nonbusiness Assets.* Ownership of Nonbusiness Assets by the distributing corporation or the controlled corporation is evidence of device. The strength of the evidence will be based on all the facts and circumstances, including the Nonbusiness Asset Percentage for each corporation. The larger the Nonbusiness Asset Percentage of either corporation, the stronger is the evidence of device. Ownership of Nonbusiness Assets ordinarily is not evidence of device if the Nonbusiness Asset Percentage of each of the distributing corporation and the controlled corporation is less than 20 percent.

(*2*) *Difference between Nonbusiness Asset Percentages.* A difference between the Nonbusiness Asset Percentage of the distributing corporation and the Nonbusiness Asset Percentage of the controlled corporation is evidence of device, and the larger the difference, the stronger is the evidence of device. Such a difference ordinarily is not itself evidence of device (but may be considered in determining the presence or the strength of other device factors) if—

(*i*) The difference is less than 10 percentage points; or

(*ii*) The distribution is not pro rata among the shareholders of the distributing corporation, and the difference is attributable to a need to equalize the value of the controlled stock and securities (if any) distributed and the value of the distributing stock and securities (if any) exchanged therefor by the distributees.

(*3*) *Cross-reference. See* paragraph (d)(5) of this section for a rule under which a distribution is considered to have been used principally as a device when the distributing corporation or the controlled corporation has a large Nonbusiness Asset Percentage and there is a large difference between Nonbusiness Asset Percentages of the two corporations.

(D) *Operating rules.* The following operating rules apply for purposes of this paragraph (d)(2)(iv):

(*1*) *Multiple controlled corporations.* If a transaction involves distributions by a distributing corporation of the stock of more than one controlled corporation, this paragraph (d)(2)(iv) applies to all such controlled corporations. If any provision in this paragraph (d)(2)(iv) requires a comparison between characteristics of the distributing corporation and the controlled corporation, the provision also requires such a comparison between the distributing corporation and each of the controlled corporations and between each controlled corporation and each other controlled corporation. If any distribution involved in the transaction is determined to have been used principally as a device by reason of this paragraph (d)(2)(iv), all distributions involved in the transaction are considered to have been used principally as a device.

(*2*) *Treatment of SAG as a single corporation.* The members of a DSAG are treated as a single corporation, the members of a CSAG are treated as a single corporation, references to the distributing corporation include all members of the DSAG, and references to the controlled corporation include all members of the CSAG.

(*3*) *Time to identify assets and determine character of assets.* The assets of the distributing corporation and the controlled corporation that are relevant in connection with this paragraph (d)(2)(iv), and the character of these assets as Business Assets or Nonbusiness Assets, must be determined by the distributing corporation and the controlled corporation immediately after the distribution. Accordingly, for purposes of this paragraph (d)(2)(iv), the assets of the distributing corporation do not include any asset, including stock of the controlled corporation, that is distributed in the transaction.

(*4*) *Time to determine fair market value of assets*—(*i*) *In general.* The distributing corporation and the controlled corporation each must determine the fair market value of its assets at the time of the distribution as of one of the following dates: Immediately before the distribution; on any date within the 60-day period before the distribution; on the date of an agreement with respect to the distribution that was binding on the distributing corporation on such date and at all times thereafter; or on the date of a public announcement or filing with the Securities and Exchange Commission with respect to the distribution.

(*ii*) *Consistency.* The distributing corporation and the controlled corporation must make the determinations described in paragraph (d)(2)(iv)(D)(*4*)(*i*) of this section in a manner consistent with each other and as of the same date for purposes of this paragraph (d)(2)(iv), paragraph (d)(5) of this section, and § 1.355–9. If these consistency requirements are not met, the fair market value of assets will be determined immediately before the distribution for purposes of all such provisions, unless the Commissioner determines that the use of such date is inconsistent with the purposes of section 355 and the regulations thereunder.

(*5*) *Fair market value.* The fair market value of an asset is determined under general federal tax principles but reduced (but not below the adjusted basis of the asset) by the amount of any liability that is described in section 357(c)(3) (relating to exclusion of certain liabilities, including liabilities the payment of which would give rise to a deduction, from the amount of liabilities assumed in certain exchanges) and relates to the asset (or to a Business with which the asset is associated). Any other liability is disregarded for purposes of determining the fair market value of an asset.

(*6*) *Interest in partnership*—(*i*) *In general.* Except as provided in paragraph (d)(2)(iv)(D)(6)(*ii*) of this section, an interest in a partnership is a Nonbusiness Asset.

(*ii*) *Exception for certain interests in partnerships.* A distributing corporation or controlled corporation may be considered to be engaged in one or more Businesses conducted by a partnership. This determination will be made using the same criteria that would be used to determine for purposes of section 355(b) and § 1.355–3 whether the corporation is considered to be engaged in the active conduct of a trade or business conducted by the partnership (relating to the corporation's ownership interest or to its ownership interest and participation in management of the partnership). If a distributing corporation or controlled corporation is considered to be engaged in one or more Businesses conducted by a partnership, the fair market value of the corporation's interest in the partnership will be allocated between Business Assets and Nonbusiness Assets in the same proportion as the proportion of the fair market values of the Business Assets and Nonbusiness Assets of the partnership.

(*7*) *Stock in corporation*—(*i*) *In general.* Except as provided in paragraph (d)(2)(iv)(D)(7)(*ii*) of this section, stock in a corporation other than a member of the DSAG or the CSAG is a Nonbusiness Asset.

(*ii*) *Exception for stock in Member of a 50-Percent-Owned Group.* If a Member of a 50-Percent-Owned Group with respect to the distributing corporation or the controlled corporation owns stock in another Member of the 50-Percent-Owned Group (other than a member of the DSAG or the CSAG, respectively), the fair market value of such stock will be allocated between Business Assets and Nonbusiness Assets in the same proportion as the proportion of the fair market values of the Business Assets and Nonbusiness Assets of the issuing corporation. This computation will be made with respect to lower-tier Members of the 50-Percent-Owned Group before the computations with respect to higher-tier members.

(*8*) *Obligation between distributing corporation or controlled corporation and certain partnerships or Members of 50-Percent-Owned Groups.* If an obligation of the distributing corporation or the controlled corporation is held by a partnership described in paragraph (d)(2)(iv)(D)(*6*)(*ii*) of this section or by a Member of its 50-Percent-Owned Group, or if an obligation of a partnership described in paragraph (d)(2)(iv)(D)(*6*)(*ii*) of this section or of a Member of its 50-Percent-Owned Group, with respect to the distributing corporation or the controlled corporation, is held by the distributing corporation or the controlled corporation, proper adjustments will be made to prevent double inclusion of assets or inappropriate allocation between Business Assets and Nonbusiness Assets of the distributing corporation or the controlled corporation on account of such obligation. *See Examples 6* and *7* of paragraph (d)(4) of this section.

(E) *Anti-abuse rule.* A transaction or series of transactions undertaken with a principal purpose of affecting the Nonbusiness Asset Percentage of any corporation will not be given effect for purposes of applying this paragraph (d)(2)(iv). For this purpose, a transaction or series of transactions includes a change in the form of ownership of an asset; an issuance, assumption, or repayment of indebtedness or other obligations; or an issuance or redemption of stock. However, this paragraph (d)(2)(iv)(E) generally does not apply to a non-transitory acquisition or disposition of assets, other than an acquisition from or disposition to a person the ownership of whose stock would, under section 318(a) (other than paragraph (4) thereof), be attributed to the distributing corporation or the controlled corporation, or to a non-transitory transfer of assets between the distributing corporation and the controlled corporation.

* * * * *

(3) * * *

(ii) *Corporate business purpose.* A corporate business purpose for the transaction is evidence of nondevice. The stronger the evidence of device (such as the presence of the device factors specified in paragraph (d)(2) of this section), the stronger the corporate business purpose must be to prevent the determination that the transaction is being used principally as a device. Evidence of device presented by ownership of Nonbusiness Assets (as defined in paragraph (d)(2)(iv)(B)(*3*) of this section) can be outweighed by the existence of a corporate business purpose for the ownership. Evidence of device presented by a difference between the Nonbusiness Asset Percentages (as defined in paragraph (d)(2)(iv)(B)(*5*) of this section) of the distributing corporation and the controlled corporation can be outweighed by the existence of a corporate business purpose for the difference. A corporate business purpose that relates to a separation of Nonbusiness Assets from one or more Businesses or Business Assets (as defined in paragraph (d)(2)(iv)(B) of this section) is not evidence of nondevice unless the business purpose involves an exigency that requires an investment or other use of the Nonbusiness Assets in one or more Businesses of the distributing corporation, the controlled corporation, or both. The assessment of the strength of a corporate business purpose will be based on all of the facts and circumstances, including, but not limited to, the following factors:

* * * * *

(4) *Examples.* The provisions of paragraphs (d)(1) through (3) of this section may be illustrated by the following examples. For purposes of these examples, A and B are individuals; P is a partnership; D and C are the distributing corporation and the controlled corporation, respectively; D and C each has no assets other than those described; there is no other evidence of device or nondevice other than as described; D has accumulated earnings and profits; and D distributes the stock of C in a distribution which, but for the issue of whether the transaction has been used principally as a device, satisfies the requirements of section 355(a).

Example 1. Sale after distribution (device). A owns all of the stock of D, which is engaged in the warehousing business. D owns all of the stock of C, which is engaged in the transportation business. All of D's and C's assets are Business Assets. D employs B, who is extremely knowledgeable of the warehousing business in general and the operations of D in particular. B has informed A that he will seriously consider leaving D if he is not given the opportunity to purchase a significant amount of stock of D. Because of his knowledge and experience, the loss of B would seriously damage the business of D. B cannot afford to purchase any significant amount of stock of D as long as D owns C. Accordingly, D distributes the stock of C to A and A subsequently sells a portion of his D stock to B. However, instead of A selling a portion of the D stock, D could have issued additional shares to B after the distribution. In light of the fact that D could have issued additional shares to B, the sale of D stock by A is substantial evidence of device. The transaction is considered to have been used principally as a device. See paragraph (d)(1), (2)(i), (ii), and (iii)(A), (B), and (D), and (3)(i) and (ii) of this section.

Example 2. Disproportionate division of Nonbusiness Assets (device)—(i) *Facts.* D owns and operates a fast food restaurant in State M and owns all of the stock of C, which owns and operates a fast food restaurant in State N. The value of the Business Assets of D's and C's fast food restaurants are $100 and $105, respectively. D also has $195 cash which D holds as a Nonbusiness Asset. D and C operate their businesses under franchises granted by competing businesses F and G, respectively. G has recently changed its franchise policy and will no longer grant or renew franchises to subsidiaries or other members of the same affiliated group of corporations operating businesses under franchises granted by its competitors. Thus, C will lose its franchise if it remains a subsidiary of D. The franchise is about to expire. The lease for the State M location will expire in 24 months, and D will be forced to relocate at that time. While D has not made any plans, it is weighing its option to purchase a building for the relocation. D contributes $45 to C, which C will retain, and distributes the stock of C pro rata among D's shareholders.

(ii) *Analysis.* After the distribution, D's Nonbusiness Asset Percentage is 60 percent ($150/$250), and C's Nonbusiness Asset Percentage is 30 percent ($45/$150). D's and C's ownership of Nonbusiness Assets of at least 20 percent of their respective Total Assets is evidence of device with respect to each. The difference between D's Nonbusiness Asset Percentage and C's Nonbusiness Asset Percentage is 30 percentage points, which is also evidence of device. The corporate business purpose for the distribution does not relate to a separation of Nonbusiness Assets from one or more Businesses or Business Assets and is evidence of nondevice. However, D has no corporate business purpose for the difference of Nonbusiness Asset Percentages. While D is considering purchasing a building for use in the State M location, this purchase is not required by any exigency. The fact that the distribution is pro rata is also evidence of device. Based on all the facts and circumstances, the transaction is considered to have been used principally as a device. See paragraph (d)(1), (2)(i), (ii), (iv)(A) and (C), and (3)(i) and (ii)(A), (B), and (C) of this section.

Example 3. Proportionate division of Nonbusiness Assets (nondevice). The facts are the same as in *Example 2,* except that D contributes $95 of the cash to C instead of $45. After the distribution, D's Nonbusiness Asset Percentage is 50 percent ($100/$200) and C's Nonbusiness Asset Percentage is 47.5 percent ($95/$200), each of which is evidence of device. The difference between D's Nonbusiness Asset Percentage and C's Nonbusiness Asset Percentage (2.5 percentage points) is less than 10 percentage points and thus is not evidence of device. The corporate business purpose for the distribution is evidence of nondevice. Based on all the facts and circumstances, the transaction is considered not to have been used principally as a device. See paragraph (d)(1), (2)(i), (ii), (iv)(A) and (C), and (3)(i) and (ii)(A), (B), and (C) of this section.

Example 4. Disproportionate division of Nonbusiness Assets (nondevice). The facts are the same as in *Example 2,* except that the lease for the State M location will expire in 6 months instead of 24 months, and D will use $80 of the $150 cash it retains to purchase a nearby building for the relocation. After the distribution, D's Nonbusiness Asset Percentage is 60 percent, and C's Nonbusiness Asset Percentage is 30 percent. D's and C's ownership of Nonbusiness Assets of at least 20 percent of their respective Total Assets is evidence of device with respect to each. The difference between D's Nonbusiness Asset Percentage and C's Nonbusiness Asset Percentage is 30 percentage points, which is also evidence of device. However, D has a corporate business purpose for a significant part of the difference of Nonbusiness Asset Percentages because D's use of $80 is required by business exigencies. The fact that the distribution is pro rata is also evidence of device. The corporate business purpose for the distribution is evidence of nondevice. Based on all the facts and circumstances, the transaction is not considered to have been used principally as a device. See paragraph (d)(1), (2)(i), (ii), (iv)(A) and (C), and (3)(i) and (ii)(A), (B), and (C) of this section.

Example 5. Nonbusiness Asset Percentage (50-Percent-Owned Group)—(i) *Facts.* C's assets consist of 50% of the stock of S1 and other assets consisting of $10,000 of Business Assets and $5,000 of Nonbusiness Assets. S1's assets consist of 40% of the stock of S2, 60% of the stock of S3 and other assets consisting of $1,000 of Business Assets and $500 of Nonbusiness Assets. S1 has $500 of liabilities, owed to unrelated persons. S2's assets consist of $500 Business Assets and $100 Nonbusiness Assets. S2 has $200 of liabilities. S3's assets consist of $3,000 Business Assets and $1,500 Nonbusiness Assets. S3 has $3,500 of liabilities, owed to unrelated persons.

(ii) *Determination of S1's Business Assets and Nonbusiness Assets.* Because C owns at least 50% of the stock of S1, S1 is a member of C's 50-Percent-Owned Group. See paragraph (d)(2)(iv)(B)(*7*) of this section. In determining the amount of C's Business Assets and Nonbusiness Assets, whether S1's stock in S2 and S3 are Nonbusiness Assets or partially Nonbusiness Assets and partially Business Assets must first be determined. See paragraph (d)(2)(iv)(D)(*7*)(*ii*) of this section (computations are made with respect to lower-tier Members of a 50-Percent-Owned Group before the computations with respect to higher-tier members). The fair market value of S1's stock in S2 is $160 (40% of $400 ($500 + $100 − $200)). Because S1 owns less than 50% of the stock of S2, S2 is not a member of C's 50-Percent-Owned Group, and thus the S2 stock is a $160 Nonbusiness Asset in the hands of S1. See paragraph (d)(2)(iv)(B)(*7*) and (D)(*7*)(*i*) of this section. The fair market value of S1's stock in S3 is $600 (60% of $1,000 ($3,000 + $1,500 − $3,500)). Because C owns at least 50% of the stock of S1 and S1 owns at least 50% of the stock of S3, S3 is a member of C's 50-Percent-Owned Group. See paragraph (d)(2)(iv)(B)(*7*) of this section. Thus, the fair market value of the S3 stock is allocated between Business Assets and Nonbusiness Assets in the same proportion as S3's proportion of Business Assets and Nonbusiness Assets. See paragraph (d)(2)(iv)(D)(*7*)(*ii*) of this section. Because S3 has Business Assets of $3,000 and Nonbusiness Assets of $1,500, this proportion is 66⅔% Business Assets ($3,000/$4,500) and 33⅓% Nonbusiness Assets ($1,500/$4,500). The $600 fair market value of S1's stock in S3 is allocated $400 to Business Assets ($600 × 66⅔%) and $200 to Nonbusiness Assets ($600 × 33⅓%). Thus, S1's assets consist of $1,400 of Business Assets ($1,000 held directly + $400 allocated from S3) and $860 of Nonbusiness Assets ($500 held directly + $160 fair market value of its S2 stock + $200 allocated from S3).

(iii) *Determination of C's Business Assets and Nonbusiness Assets.* The fair market value of C's stock in S1 is $880 (50% of $1,760 ($160 + $600 + $1,000 + $500 − $500)). Because C owns at least 50% of the stock of S1, S1 is a member of C's 50-Percent-Owned Group. See paragraph (d)(2)(iv)(B)(*7*) of this section. Thus, the fair market value of the S1 stock is allocated between Business Assets and Nonbusiness Assets in the same proportion as the proportion of S1's Business Assets and Nonbusiness Assets. See paragraph (d)(2)(iv)(D)(*7*)(*ii*) of this section. Because S1 has Business Assets of $1,400 and Nonbusiness Assets of $860, this proportion is 61.95% Business Assets ($1,400/$2,260) and 38.05% Nonbusiness Assets ($860/$2,260). The $880 fair market value of C's S1 stock is allocated $545 to Business Assets ($880 × 61.95%) and $335 to Nonbusiness Assets ($880 × 38.05%). Thus, C's assets consist of $10,545 of Business Assets ($10,000 + $545) and $5,335 of Nonbusiness Assets ($5,000 + $335), for Total Assets of $15,880. C's Nonbusiness Asset Percentage is 33.6% ($5,335/$15,880).

Example 6. Partnership interest held by Distributing. (i) *Facts.* D has directly-held Business Assets of $1,000, directly held Nonbusiness Assets of $2,000, and a 40% partnership interest in P. P has $450 of Business Assets and $1,350 of cash, which P holds as a Nonbusiness Asset, and owes a liability of $800.

(ii) *Analysis.* Pursuant to paragraph (d)(2)(iv)(D)(*6*)(*ii*) of this section, D is allocated $100 of Business Assets from P ($400 (value of D's 40% interest in P) × 25% ($450/$1,800)) and $300 of Nonbusiness Assets from P ($400 (value of D's 40% interest in P) × 75% ($1,350/$1,800)), which are added to D's directly held Business Assets and Nonbusiness Assets, respectively. D's Nonbusiness Asset Percentage is 67.6% ($2,300 Nonbusiness Assets/$3,400 Total Assets).

Example 7. Borrowing by Distributing from partnership. (i) *Facts.* The facts are the same as in Example 6, except that D borrows $500 from P and invests the proceeds in a Nonbusiness Asset. P's directly-held Nonbusiness Assets increase by $500. The D obligation is a Nonbusiness Asset in P's hands.

(ii) *Analysis.* D's directly-held Nonbusiness Assets increase by $500, to $2,500. There is no corresponding decrease in the amount of Business Assets or Nonbusiness Assets allocated to D from P, because a Nonbusiness Asset of P ($500 cash) has been replaced by another $500 Nonbusiness Asset, the obligation from D. Effectively, because D has a 40% interest in P, D has borrowed $200 (40% of $500) from itself. Accordingly, D's Nonbusiness Assets must be decreased by $200. D's Business Assets will continue to be $1,100 ($1,000 directly held plus $100 allocated from P), and D's Nonbusiness Assets will be $2,600 ($2,500 directly held, plus $300 allocated from P less the $200 decrease to prevent double inclusion of the obligation and the obligation proceeds).

* * * * *

(5) *Distributions involving separation of Business Assets from Nonbusiness Assets*—(i) *In general.* A distribution specified in paragraph (d)(5)(iii) of this section is considered to have been used principally as a device, notwithstanding the presence of nondevice factors described in paragraph (d)(3) of this section or other facts and circumstances. However, this paragraph (d)(5)(i) does not apply to a distribution that is described in paragraph (d)(3)(iv) of this section (distributions to domestic corporations entitled to certain dividends received deductions absent application of section 355(a)) or paragraph (d)(6) of this section (transactions ordinarily not considered to be a device).

(ii) *Definitions and operating rules.* The definitions in paragraph (d)(2)(iv)(B) of this section and the operating rules in paragraph (d)(2)(iv)(D) of this section apply for purposes of this paragraph (d)(5). For purposes of paragraph (d)(2)(iv)(D)(*1*), (*2*), and (*3*), references to paragraph (d)(2)(iv) of this section are treated as references to this paragraph (d)(5).

(iii) *Certain distributions involving separation of Nonbusiness Assets from Business Assets.* A distribution is specified in this paragraph (d)(5)(iii) if both—

(A) The Nonbusiness Asset Percentage of the distributing corporation or the controlled corporation is 66⅔ percent or more, and

(B) If the Nonbusiness Asset Percentage of the distributing corporation or the controlled corporation is—

(*1*) 66⅔ percent or more but less than 80 percent, and the Nonbusiness Asset Percentage of the other corporation (the controlled corporation or the distributing corporation, as the case may be) is less than 30 percent;

(*2*) 80 percent or more but less than 90 percent, and the Nonbusiness Asset Percentage of the other corporation (the controlled corporation or the distributing corporation, as the case may be) is less than 40 percent; or

(*3*) 90 percent or more, and the Nonbusiness Asset Percentage of the other corporation (the controlled corporation or the distributing corporation, as the case may be) is less than 50 percent.

(iv) *Anti-abuse rule.* The anti-abuse rule in paragraph (d)(2)(iv)(E) of this section applies for purposes of this paragraph (d)(5), with references to paragraph (d)(2)(iv) of this section treated as references to this paragraph (d)(5) and references to paragraph (d)(2)(iv)(E) of this section treated as references to this paragraph (d)(5)(iv).

(6) *Transactions ordinarily not considered as a device*—(i) *In general.* This paragraph (d)(6) specifies three distributions that ordinarily do not present the potential for federal tax avoidance described in paragraph (d)(1) of this section. Accordingly, such distributions are ordinarily considered not to have been used principally as a device, notwithstanding the presence of any of the device factors described in paragraph (d)(2) of this section or a separation of Business Assets from Nonbusiness Assets as described in paragraph (d)(5) of this section. A

transaction described in paragraph (d)(6)(iii) or (iv) of this section is not protected by this paragraph (d)(6) from a determination that it was used principally as a device if it involves the distribution of the stock of more than one controlled corporation and facilitates the avoidance of the dividend provisions of the Code through the subsequent sale or exchange of stock of one corporation and the retention of the stock of another corporation. * * *

* * * * *

(i) *Effective/applicability date*—(1) *Paragraph (d) of this section*—(i) *In general.* Except as provided in paragraph (i)(1)(ii) of this section, paragraph (d) of this section applies to transactions occurring on or after the date the Treasury decision adopting these regulations as final regulations is published in the **Federal Register**.

(ii) *Transition rule.* Paragraph (d) of this section does not apply to a distribution that is—

(A) Made pursuant to an agreement, resolution, or other corporate action that is binding on or before the date the Treasury decision adopting these regulations as final regulations is published in the **Federal Register** and at all times thereafter;

(B) Described in a ruling request submitted to the Internal Revenue Service on or before July 15, 2016; or

(C) Described in a public announcement or filing with the Securities and Exchange Commission on or before the date the Treasury decision adopting these regulations as final regulations is published in the **Federal Register**.

(2) *Paragraph (g) of this section.* Paragraph (g) of this section applies to distributions occurring after October 20, 2011. For rules regarding distributions occurring on or before October 20, 2011, *see* § 1.355–2T(i), as contained in 26 CFR part 1, revised as of April 1, 2011.

■ **Par. 5.** Reserved § 1.355–8 is added to read as follows:

§ 1.355–8 [Reserved]

■ **Par. 6.** Section 1.355–9 is added to read as follows:

§ 1.355–9 Minimum percentage of Five-Year-Active-Business Assets.

(a) *Definitions.* The following definitions apply for purposes of this section:

(1) *Distributing, Controlled. Distributing* means the distributing corporation within the meaning of § 1.355–1(b). *Controlled* means the controlled corporation within the meaning of § 1.355–1(b).

(2) *Five-Year-Active Business. Five-Year-Active Business* means the active conduct of a trade or business that satisfies the requirements and limitations of section 355(b)(2) and § 1.355–3(b).

(3) *Five-Year-Active-Business Assets. Five-Year-Active-Business Assets* of a corporation means its gross assets used in one or more Five-Year-Active Businesses. Such assets include cash and cash equivalents held as a reasonable amount of working capital for one or more Five-Year-Active Businesses. Such assets also include assets required (by binding commitment or legal requirement) to be held to provide for exigencies related to a Five-Year-Active Business or for regulatory purposes with respect to a Five-Year-Active Business. For this purpose, such assets include assets the holder is required (by binding commitment or legal requirement) to hold to secure or otherwise provide for a financial obligation reasonably expected to arise from a Five-Year-Active Business and assets held to implement a binding commitment to expend funds to expand or improve a Five-Year-Active Business.

(4) *Non-Five-Year-Active-Business Assets. Non-Five-Year-Active-Business Assets* of a corporation means its gross assets other than its Five-Year-Active-Business Assets.

(5) *Total Assets. Total Assets* of a corporation means its Five-Year-Active-Business Assets and its Non-Five-Year-Active-Business Assets.

(6) *Five-Year-Active-Business Asset Percentage.* The *Five-Year-Active-Business Asset Percentage* of a corporation is the percentage determined by dividing the fair market value of its Five-Year-Active-Business Assets by the fair market value of its Total Assets.

(7) *Separate Affiliated Group, SAG, CSAG, and DSAG. Separate Affiliated Group* (or *SAG*), *CSAG,* and *DSAG* have the same meanings as in § 1.355–2(d)(2)(iv)(B)(*6*).

(b) *Five percent minimum Five-Year-Active-Business Asset Percentage.* For the requirements of section 355(a)(1)(C) and section 355(b) to be satisfied with respect to a distribution, the Five-Year-Active-Business Asset Percentage of each of Distributing and Controlled must be at least five percent.

(c) *Operating rules.* The following operating rules apply for purposes of this section:

(1) *Treatment of SAG and fair market value.* The operating rules in § 1.355–2(d)(2)(iv)(D)(*2*) (treatment of SAG as a single corporation) and (*5*) (fair market value) apply.

(2) *Time to identify assets, determine character of assets, and determine fair market value of assets.* The provisions of § 1.355–2(d)(2)(iv)(D)(*3*) (time to identify assets and determine character of assets) apply, except that references to paragraph (d)(2)(iv) are treated as references to this section and "Business Assets or Nonbusiness Assets" is replaced with "Five-Year-Active-Business Assets or Non-Five-Year-Active-Business Assets," and the provisions of § 1.355–2(d)(2)(iv)(D)(*4*) (time to determine fair market value of assets) apply.

(3) *Interest in partnership*—(i) *In general.* Except as provided in paragraph (c)(3)(ii) of this section, an interest in a partnership is a Non-Five-Year-Active-Business Asset.

(ii) *Exception for certain interests in partnerships.* If Distributing or Controlled is considered to be engaged in one or more Five-Year-Active-Businesses conducted by a partnership, the fair market value of the corporation's interest in the partnership will be allocated between Five-Year-Active-Business Assets and Non-Five-Year-Active-Business Assets in the same proportion as the proportion of the fair market values of the Five-Year-Active-Business Assets and Non-Five-Year-Active-Business Assets of the partnership.

(d) *Anti-abuse rule.* A transaction or series of transactions undertaken with a principal purpose of affecting the Five-Year-Active-Business Asset Percentage of any corporation will not be given effect for purposes of applying this § 1.355–9. For this purpose, a transaction or series of transactions includes a change in the form of ownership of an asset; an issuance, assumption, or repayment of indebtedness or other obligations; or an issuance or redemption of stock. However, this paragraph (d) generally does not apply to a non-transitory acquisition or disposition of assets, other than an acquisition from or disposition to a person the ownership of whose stock would, under section 318(a) (other than paragraph (4) thereof), be attributed to Distributing or Controlled, or to a non-transitory transfer of assets between Distributing and Controlled.

(e) *Effective/applicability date*—(1) *In general.* Except as provided in paragraph (e)(2) of this section, this section applies to transactions occurring on or after the date the Treasury decision adopting these regulations as final regulations is published in the **Federal Register**.

(2) *Transition rule*—This section does not apply to a distribution that is—

(i) Made pursuant to an agreement, resolution, or other corporate action that is binding on or before the date the

Treasury decision adopting these regulations as final regulations is published in the **Federal Register** and at all times thereafter;

(ii) Described in a ruling request submitted to the Internal Revenue Service on or before July 15, 2016; or

(iii) Described in a public announcement or filing with the Securities and Exchange Commission on or before the date the Treasury decision adopting these regulations as final regulations is published in the **Federal Register**.

John Dalrymple,

Deputy Commissioner for Services and Enforcement.

[FR Doc. 2016–16512 Filed 7–14–16; 8:45 am]

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DEPARTMENT OF JUSTICE

28 CFR Part 32

[Docket No.: OJP (BJA) 1716]

RIN 1121–AA85

Public Safety Officers' Benefits Program

AGENCY: Office of Justice Programs, Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: This rule proposes to make the following changes to current regulations implementing the Public Safety Officers' Benefits (PSOB) Act: Adopting the World Trade Center (WTC) Health Program's List of WTC-Related Health Conditions (List), the WTC Health Program's standards for certifying that an injury is covered for treatment under the Program, and related regulatory provisions, establishing payment offset provisions between the PSOB Program and the September 11th Victim Compensation Fund, and revising the provisions that define when the statutory presumption of line-of-duty death resulting from certain heart attacks, strokes, and vascular ruptures is rebutted. The proposed changes based on the WTC Health Program's List and related provisions would provide a means for claimants to establish that certain public safety officers with chronic, often latent, health conditions sustained a line-of-duty injury under the PSOB Act. The proposed payment offset provisions are intended to implement statutory amendments to the PSOB Act requiring such offset and to facilitate claims processing. Similarly, the proposed rule implementing the statutory presumption associated with certain heart attacks, strokes, and vascular ruptures is intended to amend the current regulation to conform to recent amendments to the PSOB Act and to improve the processing of such claims.

DATES: Written comments must be postmarked and electronic comments must be submitted on or before September 13, 2016. Comments received by mail will be considered timely if they are postmarked on or before that date. The electronic Federal Docket Management System (FDMS) will accept comments until Midnight Eastern Time at the end of that day.

ADDRESSES: Please address all comments regarding this rule by U.S. mail, to: Hope Janke, Bureau of Justice Assistance, Office of Justice Programs, 810 7th Street NW., Washington, DC 20531; or by telefacsimile to (202) 354–4135. To ensure proper handling, please reference OJP Docket No. 1716 on your correspondence. Comments may also be sent electronically through *http://regulations.gov* using the electronic comment form provided on that site. An electronic copy of this document is also available at the *http://regulations.gov* Web site. OJP will accept attachments to electronic comments in Microsoft Word, WordPerfect, or Adobe PDF formats only.

FOR FURTHER INFORMATION CONTACT: Hope Janke, BJA, OJP, at (202) 514–6278, or toll-free at 1 (888) 744–6513.

SUPPLEMENTARY INFORMATION:

I. Posting of Public Comments

Please note that all comments received are considered part of the public record and made available for public inspection online at *http://www.regulations.gov*. Information made available for public inspection includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter.

The Office of Justice Programs (OJP) does not require commenters to submit personal identifying information (such as your name, address, medical information, etc.) as part of your comment. However, if you wish to submit such information, but do not wish it to be posted online, you must include the phrase "PERSONAL IDENTIFYING INFORMATION" in the first paragraph of your comment. You must also locate all the personal identifying information that you do not want posted online in the first paragraph of your comment and identify what information you want the agency to redact. Personal identifying information identified and located as set forth above will be placed in the agency's public docket file, but not posted online.

If you wish to submit confidential business information as part of your comment but do not wish it to be posted online, you must include the phrase "CONFIDENTIAL BUSINESS INFORMATION" in the first paragraph of your comment. You must also prominently identify confidential business information to be redacted within the comment. If a comment has so much confidential business information that it cannot be effectively redacted, the agency may choose not to post that comment (or to only partially post that comment) on *http://www.regulations.gov*. Confidential business information identified and located as set forth above will not be placed in the public docket file, nor will it be posted online.

If you wish to inspect the agency's public docket file in person by appointment, please see the **FOR FURTHER INFORMATION CONTACT** paragraph.

II. Background

A. General

The Public Safety Officers' Benefits (PSOB) Program, 42 U.S.C. 3796 *et seq.* (established pursuant to the Public Safety Officers' Benefits Act of 1976), is administered by the Bureau of Justice Assistance (BJA) of the Office of Justice Programs (OJP), U.S. Department of Justice. Generally speaking, the PSOB Program provides a one-time financial payment to the statutorily-eligible survivors of public safety officers who die as the direct and proximate result of personal injuries sustained in the line of duty, as well as educational assistance for their spouses and eligible children.

Alternatively, the PSOB Program also provides a one-time financial payment directly to public safety officers determined to be permanently and totally disabled as the direct and proximate result of personal injury sustained in the line of duty, as well as educational assistance for their spouses and eligible children.

B. Establishing a Line-of-Duty Injury Under the PSOB Act and Implementing Regulations

42 U.S.C. 3796(a) authorizes the payment, to statutory survivors, of a benefit of $250,000, currently adjusted for inflation at $339,881, when the administering agency determines, under its regulations "that a public safety officer has died as the direct and proximate result of a personal injury sustained in the line of duty." Similarly, 42 U.S.C. 3796(b) authorizes the agency

to pay the same inflation-adjusted benefit, when it determines, under its regulations, that a public safety officer has "become permanently and totally disabled as the direct and proximate result of a personal injury sustained in the line of duty." The agency has exercised its regulatory authority in regulations published in 28 CFR part 32 defining, among other things, "injury," "line of duty injury," and "direct and proximate result of an injury." Those regulations specify the criteria that must be met in the ordinary course for a claimant to establish that a public safety officer sustained a line-of-duty injury and that the injury caused the officer's death or permanent and total disability.

Under the definition of injury in 28 CFR 32.3, a claimant must establish that a public safety officer sustained a "traumatic physical wound (or a traumatized physical condition of the body) directly and proximately caused by external force." Under definitions related to causation in 28 CFR 32.3 (defining direct and proximate result of an injury and substantial factor), a claimant must also establish that the injury was the "substantial factor" in the officer's death or disability. "A factor substantially brings about a death, injury, [or] disability" if it was sufficient in and of itself to cause the death, injury, or disability, or no other factor (or combination of factors) "contributed to the death, injury, [or] disability . . . to so great a degree as it did." 28 CFR 32.3 (defining substantial factor). Taken together, these regulations require that a claimant seeking benefits establish an injury, *i.e.,* a traumatic physical wound or traumatized physical condition of the body directly and proximately caused by an external force or other agent, *e.g.,* chemicals, as well as a death or disability, and a direct and proximate causal nexus between the injury and the death or disability.

In PSOB claims involving acute injuries caused by readily identifiable external forces such as a gunshot, motor vehicle accident, or other trauma with death occurring simultaneously or closely following injury, a claimant's burden in establishing the injury and causal link between injury and death may be straightforward and readily demonstrated. In such cases, a death certificate or an autopsy is generally sufficient to establish a traumatic wound or traumatized condition, the external force that caused the wound or condition, the officer's death, and a direct and proximate causal link between the injury and death.

In PSOB claims asserting injury or death resulting from exposure to unspecified toxins or hazards associated with line-of-duty activity, however, an autopsy may not sufficiently identify the mechanism of the injury, or adequately establish the direct and proximate causal link between the injury and the death (or permanent and total disability) necessary to support the approval of a claim under the PSOB Act. In such claims, more detailed medical evaluation may be required, and substantial medical evidence may need to be gathered and produced before PSOB determining officials may make the necessary findings to find the PSOB Act standards are met. For example, an autopsy usually is not sufficient evidence when the claims are based on the chronic, often latent, illnesses and conditions of 9/11 first responders; *e.g.,* respiratory disorders and certain cancers. Similar burdens in gathering, producing, and evaluating medical evidence exist for 9/11 first responders claiming to be permanently and totally disabled as a result of exposure to unidentified toxins or hazards encountered in responding to the September 11, 2001, terrorist attacks.

C. Establishing Injury Under the James Zadroga 9/11 Health and Compensation Act of 2010

Pursuant to the James Zadroga 9/11 Health and Compensation Act of 2010 (Pub. L. 111–347), as amended, the World Trade Center (WTC) Health Program, which is administered by the Director of the National Institute for Occupational Safety and Health (NIOSH), within the Centers for Disease Control and Prevention (a component of the U.S. Department of Health and Human Services), provides medical monitoring and treatment for WTC Health Program members with certain health conditions that are certified as related to the unique circumstances of the 9/11 explosions, ensuing conflagrations, and clean-up (9/11 disaster).[1] In so doing, the Administrator of the WTC Health Program has an advisory committee including medical and scientific experts appointed to review and consider the latest research on connections that may exist between various medical conditions and exposure to the 9/11 disaster. The Administrator of the WTC Health Program may seek guidance and recommendations from these medical and scientific experts, in determining whether to propose adding conditions to the List of WTC-Related Health Conditions through rulemaking.

The List of WTC-Related Health Conditions is a list of illnesses or health conditions that, pursuant to an examination by a medical professional with expertise in treating or diagnosing the listed conditions, may be found to be related to a WTC Health Program member's exposure to airborne toxins, any other hazards, or any other adverse conditions resulting from the September 11, 2001, terrorist attacks. That a WTC Health Program member has a health condition or illness on the List of WTC-Related Health Conditions does not, by itself, establish that such health condition or illness was related to the 9/11 disaster and, therefore, is eligible for treatment in the WTC Health Program. Rather, the WTC Health Program also makes a specific decision as to whether a particular WTC Health Program member's exposure to the toxins, hazards, or other adverse conditions associated with the 9/11 disaster was "substantially likely to be a significant factor in aggravating, contributing to, or causing the illness or health condition." 42 U.S.C. 300mm–22(a)(1)(A)(1). By law, such decision is based on an assessment of: (1) The individual's exposure to airborne toxins, any other hazard, or any other condition resulting from the terrorist attacks; and (2) the type of symptoms and temporal sequence of symptoms. 42 U.S.C. 300mm–22(a)(2). Together, the List of WTC-Related Health Conditions and individual assessment as to exposure and symptomatology comprise the general and specific findings that the WTC Health Program makes in establishing that a WTC Health Program member's particular illness or health condition is related to the 9/11 disaster.

D. Fatal Heart Attacks, Strokes, and Vascular Ruptures Under 42 U.S.C. 3796(k)

To establish eligibility for death benefits under the PSOB Act, claimants must establish that a public safety officer suffered a personal injury in the line of duty that directly and proximately caused the officer's death. This statutory requirement excluded from coverage those conditions caused by stress and strain and occupational disease, such as practically speaking, most heart attacks and strokes.

The Hometown Heroes Survivors' Benefits Act of 2003 (Pub. L. 108–182) (Hometown Heroes Act) amended the PSOB Act by creating a statutory presumption in 42 U.S.C. 3796(k) of death by a line-of-duty injury, which may be rebutted by "competent medical evidence to the contrary," in cases where a public safety officer dies of heart attack or stroke while engaging in, (or within 24 hours of engaging in) "nonroutine stressful or strenuous physical [line-of-duty] activity." Implementation of the rebuttal language has proved challenging for OJP. In fact, the House Judiciary Committee in 2012 noted that "[one] particular term introduced into the PSOBA in 2003, 'competent medical evidence to the contrary,' has not proven workable as introduced." [2]

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[1] The James Zadroga 9/11 Health and Compensation Act of 2010 was amended by the Consolidated Appropriations Act, 2016, Public Law 114–113 (Dec. 18, 2015) (The James Zadroga 9/11 Health and Compensation Reauthorization Act) (available at *gpo.gov*).

In 2006 and 2008, OJP published final rules implementing the Hometown Heroes Act. The 2008 rule provided that the presumption attaches "unless it . . . is overcome by competent medical evidence to the contrary, when evidence indicates to a degree of medical probability that extrinsic circumstances, considered in combination (as one circumstance) or alone, were a substantial factor in bringing the heart attack or stroke about." [3] The rule defined extrinsic circumstances as "[a]n event or events; or . . . [a]n intentional risky behavior or intentional risky behaviors." Thus, under regulations implementing the previous presumption, the presumption was rebutted when competent medical evidence of record established that an event(s) or intentional risky behavior(s) [4] (as defined in the regulations) were the substantial factor in an officer's fatal heart attack or stroke.

OJP's experience is that consideration of cardiovascular disease risk factors and the concept of "risky behavior" have largely proven unworkable. In practice, medical examiners, even with a complete medical record, are rarely able to determine with medical precision whether an inadequately treated cardiovascular disease risk factor(s) was the substantial factor in the officer's fatal condition. As a result, the PSOB Program has expended significant time and resources on inconclusive results, *i.e.,* claims in which a recognized cardiovascular disease risk factor is found to have somehow contributed to the officer's fatal condition but not to the degree that it rebutted the presumption. OJP's conclusion that the current interpretation is unworkable is further reflected in the low numbers of claims it has denied based on "risky behaviors." Despite routinely seeking from claimants additional medical evidence and engaging in time-consuming independent medical review of such evidence, from Fiscal Year 2011 to date, BJA denied at the PSOB Office level less than 1% of all Hometown Heroes claims determined on the basis that an officer's "risky behaviors" were a substantial factor in bringing about the heart attack, stroke, or vascular rupture.

In January 2013, the Dale Long Public Safety Officers' Benefits Improvement Act of 2012 (Section 1086 of Pub. L. 112–239) (Dale Long Act) amended the rebuttal language in section 3796(k). As amended, the presumption is rebutted when "competent medical evidence establishes that the [public safety officer's] heart attack, stroke, or vascular rupture was unrelated to the [officer's] engagement or participation or was directly and proximately caused by something other than the mere presence of cardiovascular-disease risk factors." As the amendment repealed the statutory language upon which OJP regulations implementing the presumption are based, *e.g., Competent medical evidence to the contrary,* such regulations are now obsolete.

III. Provisions of the Proposed Rule

A. Adoption of the WTC Health Program's List of WTC-Related Health Conditions and Standards

Because of the medical and scientific evaluation that informs the List of WTC-Related Health Conditions (List), BJA proposes to use the List as a means for streamlining its own claim-specific evaluation, where a claim for PSOB Program benefits is based on a medical condition (not otherwise excluded from coverage under the PSOB Program) included in the List. Similarly, BJA also proposes, consistent with the law, regulations, policies, and procedures governing the WTC Health Program's certification of an individual's injuries as covered for treatment under the Program, and in conjunction with the List, to assess the individual public safety officer's exposure to toxins, hazards, and other adverse conditions resulting from the terrorist attacks as well as the type of symptoms and temporal sequence of symptoms. Under the proposed rule, BJA will independently use the WTC Health Program's "standards" for certification, which includes the Program's regulations, policies, and procedures, to establish an injury under the PSOB Act.

The proposed rule would establish a means by which claimants could establish that a public safety officer who suffered physical injury as a result of line-of-duty activity at a 9/11 crash site sustained an injury under the PSOB Act. More specifically, the rule would adopt the WTC Health Program standards for establishing injury or illness for public safety officers who responded to the 9/11 disaster based on the medical and scientific evidence underlying those standards and to promote consistency in the process for determining claims resulting from exposure to a 9/11 crash site. Under the proposed rule, evidence demonstrating that a public safety officer (1) performed line-of-duty activity at a 9/11 crash site, (2) was diagnosed with a physical illness or condition on the List of WTC-Related Health Conditions as defined in 42 CFR part 88, (3) whose physical injury was directly and proximately caused by an illness or condition on the List, and (4) whose exposure to the hazards, toxins, and adverse conditions of the 9/11 disaster are found by the PSOB determining official to be substantially likely to have been a significant factor in aggravating, contributing to, or causing the responder's health condition, would establish an injury for purposes of the PSOB Act. Consistent with the VCF, which payments are treated by law as duplicative of PSOB Program payments and required to be offset, 42 U.S.C. 3796(f)(3), a claimant's injury would be limited to "physical harm" as defined 28 CFR 104.2(c).

BJA proposes to adopt the List of WTC-Related Health Conditions (other than mental health conditions) because these are illnesses or health conditions for which exposure to airborne toxins, any other hazard, or any other adverse condition resulting from the September 11, 2001, terrorist attacks, have been found by another federal program to potentially be related to 9/11 exposures. Because the PSOB Program already excludes mental health conditions from its coverage, the proposed rule would not extend its application to any mental health conditions on the List.

In addition, the adoption of the List and the WTC Health Program standards for assessing injury is warranted based on the unique circumstances associated with the response to the 9/11 disaster, the chronic, often latent, nature of health conditions linked to the response, and the rigorous evidentiary burden faced by PSOB claimants in establishing an injury under current regulations implementing the PSOB Act. PSOB claimants would still be required to satisfy the statutory requirement that such injury have been the direct and proximate cause of the public safety officer's death or permanent and total disability.

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[2] H.R. Rpt. 112–548 at 14 (June 25, 2012).

[3] 28 CFR 32.13 (defining *Competent medical evidence to the contrary*).

[4] In general, "risky behavior" was defined as (1) an officer's failure to undertake treatment, without reasonable excuse, of any known commonly accepted cardiovascular disease risk factor exceeding minimum high-risk levels or of diseases associated with increased risk of cardiovascular disease, or where certain biological relatives had a history of cardiovascular disease, (2) consumption over certain levels of cigarettes or alcohol, and (3) use or abuse of certain controlled substances associated with increased risk of cardiovascular disease.

The proposed rule would cover those circumstances in which a claimant lacked a WTC Health Program certification or its equivalent, *e.g.*, a determination by the Victim Compensation Fund that an individual's injury was eligible for compensation, that a public safety officer's 9/11 exposure is substantially likely to have been a significant factor in aggravating, contributing to, or causing a particular health condition. The proposed rule would also codify OJP's interpretation that its current regulations providing that a PSOB determining official may consider the factual findings of a public agency, 28 CFR 32.5(b), enable the PSOB Program to accept as evidence of a line-of-duty injury a "certification" by the WTC Program Administrator, as defined in 42 CFR 88.1, or its equivalent, that a particular public safety officer's exposure to airborne toxins, any other hazards, or any other adverse conditions resulting from the September 11, 2001, terrorist attacks is substantially likely to be a significant factor in aggravating, contributing to, or causing the condition.

This regulatory approach would promote the efficient resolution of issues related to injury (and in some cases, causation) without the need for the PSOB Program to conduct an individual review and investigation of the available medical literature in every claim associated with a 9/11 injury. It would promote consistency in federal decision making by allowing the complex medical decisions of another federal program (the WTC Health Program) to streamline the PSOB Program's own evaluation of the same medical issues. It also would lessen the burden on claimants who otherwise may face significant challenges in obtaining and producing significant medical documentation necessary to establish an injury.

Under the proposed rule, the PSOB Program would rely upon and apply the List and WTC Health Program standards to its independent determination of injury only where the claimant otherwise has established all of the applicable elements normally required for a PSOB claim; *e.g.*, proof of status as a public safety officer and line-of-duty activity.

To maintain consistency with the September 11th Victim Compensation Fund of 2001 (VCF), as amended,[5] the proposed rule would incorporate certain relevant definitions found in the James Zadroga 9/11 Health and Compensation Act of 2010, Public Law 111–347, as amended, and definitions found in implementing regulations: "Physical harm, and "WTC-related health condition." In particular, OJP proposes to adopt the physical harm provision, which requires that the physical condition upon which the claim of injury is based was treated by a medical professional and may be verified by medical records that were created by or at the direction of the medical care provider, for purposes of maintaining the integrity of the PSOB Program.

B. Prohibition Against Duplicate (Dual) Payments

The 2013 amendment to the PSOB Act established, in the PSOB Act itself, a limitation on payments by declaring that benefit payments made under the PSOB Act are in addition generally to any other benefit except payments under the VCF. 42 U.S.C. 3796(f)(3). Therefore, OJP proposes to add a new provision in 28 CFR 32.6, describing how and when the PSOB Program would pay benefits under the PSOB Act to persons who have received payments from the VCF.

Under the proposed rule, no death or disability benefits under the PSOB program would be payable when the VCF has made payments to or with respect to a public safety officer that are equal to or exceed the amount of such benefits payable under the PSOB Act. To account for circumstances when a PSOB claimant has a pending claim for VCF benefits, or the VCF has made payment to a PSOB claimant that is less than the amount payable under the PSOB Act, the proposed rule would clarify that nothing in the PSOB Act or the rule itself precludes payment of PSOB benefits before the VCF makes payment of compensation. In so doing, the PSOB Program could pay benefits to VCF claimants without waiting for the VCF to issue its payments. To prevent overpayments and ensure the offset is applied, before the PSOB Program pays any benefits based on injuries sustained in the 9/11 disaster, it would verify with the VCF the amount of any payments made or payable to a VCF claimant.

The proposed rule would also clarify that the offset does not extend to educational assistance payable under the PSOB Act, 42 U.S.C. 3796d—3796d–7. When viewed in the context of a statutory scheme providing for the payment of a particular one-time death or disability benefit, the agency believes that the ordinary meaning of "the benefit payable under this subchapter" suggests that the scope of the offset is limited to the death and disability benefit payable under 42 U.S.C. 3796. However, under current regulations that were promulgated before the offset statute was enacted, educational assistance may, with one exception, be paid only when PSOB Program death or disability benefits have been paid. As OJP has determined the offset does not extend to educational assistance, the proposed rule would revise the definition of "Eligible public safety officer" in current § 32.33 to authorize payment of educational assistance where death or disability benefits would have been paid but for the operation of the offset in 42 U.S.C. 3796(f).

C. Fatal Heart Attacks, Strokes, and Vascular Ruptures Under 42 U.S.C. 3796(k)

As the Dale Long Act has amended 42 U.S.C. 3796(k), OJP proposes to amend its implementing regulations in 28 CFR 32.13 and 32.14 to reflect the revised statutory language. In implementing revised section 3796(k), the proposed rule would define in proposed § 32.13 the two circumstances when the presumption of death directly and proximately resulting from a line-of-duty injury associated with certain heart attacks, strokes, and vascular ruptures as provided in section 3796(k) is rebutted—*i.e.*, when "competent medical evidence establishes that the [officer's] heart attack, stroke, or vascular rupture [1] was unrelated to the [officer's] engagement or participation or [2] was directly and proximately caused by something other than the mere presence of cardiovascular-disease risk factors."

Under the proposed rule, an officer's heart attack, stroke, or vascular rupture would be considered as "unrelated to an [officer's] engagement or participation" if competent medical evidence established that an independent event or occurrence significantly contributed in bringing about the officer's heart attack, stroke, or vascular rupture. OJP believes that defining this rebuttal factor in terms of "an independent event or occurrence," that is, something that happens to an officer, appropriately ensures that an off-duty heart attack, stroke, or vascular rupture caused by a clearly unrelated event, such as an off-duty officer's accident, is not covered by the presumption.

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[5] The September 11th Victim Compensation Fund of 2001 was amended by the by the Consolidated Appropriations Act, 2016, Public L. 114–113 (Dec. 18, 2015) (The James Zadroga 9/11 Victim Compensation Fund Reauthorization Act) (available at *gpo.gov*).

For example, a police officer's fatal heart attack due to electrocution suffered while performing home repair, established by competent medical evidence, would not be covered by the presumption despite occurring only 12 hours after the officer engaged in a situation involving nonroutine stressful or strenuous physical law enforcement activity. The heart attack is not covered by the presumption because competent medical evidence establishes that an independent event or occurrence (electrocution sustained while repairing home wiring) separate and apart from the officer's qualifying activity, *i.e.*, engagement in a situation involving nonroutine stressful or strenuous physical law enforcement activity, significantly contributed in bringing about the officer's fatal heart attack. At the same time, such a construction would ensure that an officer's ordinary and routine off-duty activities such as yard work or exercise, that take place following qualifying, on-duty engagement or participation, would not be evaluated for their contribution to the officer's fatal heart attack, stroke, or vascular rupture.

Turning to the other rebuttal factor in the proposed rule, an officer's heart attack, stroke, or vascular rupture would be considered to be caused by "something other than the mere presence of cardiovascular-disease risk factors" when competent medical evidence establishes that the officer's heart attack, stroke, or vascular rupture was directly and proximately caused by the officer's ingestion of controlled substances on Schedule I of the drug control and enforcement laws or the officer's abuse of controlled substances on Schedules II–V of the drug control and enforcement laws. OJP believes that by defining this particular rebuttal factor in terms of intentional behaviors that are well established as adversely affecting cardiovascular health, that exceed the mere presence of cardiovascular disease risk factors, and that are readily attributable to an officer's actions, the proposed rule would appropriately rebut the presumption and preclude payment consistent with the language of the statute.

In addition to implementing the amended statutory language of the presumption, the proposed changes to § 32.13 would reduce the evidentiary burden on claimants seeking death benefits under section 3796(k) and streamline the processing of such claims by reducing the circumstances under which the PSOB Program would seek expert medical review and additional medical evidence. Towards this end, the proposed rule would eliminate as a basis for rebutting the presumption certain actions of the officer previously defined in regulations as "risky behaviors," *e.g.*, an officer's failure to adequately treat known cardiovascular-disease risk factors. OJP believes that eliminating this basis for rebuttal is justified based on its experience implementing the previous regulation which revealed that medical examiners, even with a complete medical record, itself a rare occurrence, were rarely able to determine whether a public safety officer was sufficiently non-compliant with treatment such that it could be said to be the direct and proximate cause of the officer's fatal heart attack, stroke, or vascular rupture. By omitting from the proposed rule those rebuttal factors which often required the collection and evaluation of extensive medical records as part of an independent medical examination and produced largely inconclusive results, the proposed rule would measurably reduce the burden on claimants and the agency.

Consistent with the amendments to the statutory rebuttal provision, the proposed rule would also eliminate from § 32.13 provisions defining "Competent medical evidence to the contrary," "Excessive consumption of alcohol," "Extrinsic circumstances," "Risky behavior," and "Undertaking of treatment." In addition, the proposed rule would eliminate § 32.14(c), requiring the PSOB Office to provide notice to claimants when it determines the existence of competent medical evidence to the contrary. As the statute no longer includes such language, the provision is unnecessary.

IV. Regulatory Requirements

Executive Order 12866 and 13563—Regulatory Planning and Review

This proposed rule has been drafted and reviewed in accordance with Executive Order 12866, "Regulatory Planning and Review," section 1(b), Principles of Regulation, and in accordance with Executive Order 13563, "Improving Regulation and Regulatory Review," section 1(b), General Principles of Regulation. Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). As explained below, OJP has assessed the costs and benefits of this proposed rule as required by Executive Order 12866 and has determined that the benefits of the proposed rule justify the costs.

A. Adoption of the WTC Health Program's List and Standards

OJP's experience is that PSOB claimants have been largely unsuccessful in establishing an "injury" for delayed-onset medical conditions or illnesses, particularly cancer. As the proposed rule establishes an evidentiary standard intended for the unique circumstances of public safety officers who sustained an injury related to the 9/11 disaster, OJP estimates that the proposed rule would likely affect all of the 29 claims based on 9/11 injury (27 death/2 disability) currently pending in the PSOB Program without a WTC Health Program certification or its equivalent by enabling these claimants to establish an "injury" under the PSOB Act. Although there are currently 161 total PSOB death and disability claims pending with assertions of injuries based on 9/11 exposure, this estimate pertains only to the 29 claims not covered under OJP's current regulatory authority, as benefits paid through OJP's process of determining PSOB claims based on "certifications" issued by the WTC Health Program Administrator (or equivalent) under 28 CFR 32.5(b) would not be impacted as a result of this regulatory change.

If all 29 such claims were paid, the total PSOB Program death and disability benefit cost would be $8,778,198.80. Based on amounts appropriated in FY2016 for PSOB Program death benefits ("such sums as necessary"—estimated at $71,323,000) and disability and education benefits ($16,300,000), OJP knows that it could pay the death claims from its current appropriations, and estimates that it could pay the disability claims from its current appropriations. OJP's estimate does not account for any offset to PSOB Program payments based on VCF payments, which would reduce the amount of PSOB Program payments made; however, OJP is unable to estimate how many of the 29 claims would be approved by VCF. Regardless of whether a PSOB payment were offset by a VCF payment, there is no additional benefit cost, as the amounts that would be required are covered by current appropriations (with respect to death claims) and appear to be covered by such appropriations with respect to disability claims, and, barring unforeseen circumstances, would not exceed such amounts. As PSOB claims based on 9/11 injury would be processed by existing staff, OJP would not incur additional administrative or personnel costs in processing these claims.

B. Provisions Implementing the Offset at 42 U.S.C. 3796(f)(3)

The primary benefit of the proposed rule is that, pursuant to statute, it permits the PSOB Program to pay benefits to PSOB claimants who are awaiting a decision on eligibility for VCF benefits, pending receipt of VCF payments, or are in receipt of VCF payments less than the maximum PSOB Program death or disability payment. A secondary benefit is that it clarifies that claimants who would be eligible for payment of death or disability benefits under the PSOB Act but for the operation of the offset, would be eligible for educational assistance.

Estimating annual costs for public safety officers' educational assistance is difficult because of the nature of the payment.[6] If all of the 29 currently pending claims based on 9/11 injury and lacking a WTC Health Program certification, or its equivalent, were approved, thereby creating potential eligibility for educational assistance, OJP estimates that the impact could be to add approximately 49 educational assistance claimants for FY2016 and beyond. Using the current maximum monthly payment rate of $1,021/month, OJP estimates that annual benefit costs could increase by approximately $450,261, annually (based on 49 claimants completing 9 months of educational assistance payable at the current maximum rate of $1,021/month).[7] Based on the amount of funds appropriated for disability benefits and educational assistance in FY2016 ($16,300,000), OJP estimates that, barring unforeseen circumstances, it could pay these additional education claims from its current appropriation. As PSOB claims based on 9/11 injury would be processed by existing staff, OJP would not incur additional costs in processing these claims.

C. Fatal Heart Attacks, Strokes, and Vascular Ruptures Under 42 U.S.C. 3796(k)

The primary benefit of the proposed rule is the reduced burden on both claimants and the agency in determining claims under 42 U.S.C. 3796(k). In defining the circumstances that warrant rebuttal in terms of readily ascertainable facts, OJP believes that the PSOB Program will, in most cases, be able to rely upon the evidence of injury and death ordinarily submitted with a claim, *e.g.*, a death certificate or autopsy. Based on its experience, OJP estimates that, under the previous regulatory interpretation, it seeks additional evidence from claimants and independent medical review of medical evidence in approximately 50 percent of claims. Under the proposed rule, OJP estimates that the PSOB Program would need to seek additional evidence from claimants and independent medical review of medical evidence in less than 5 percent of claims. As the PSOB Program receives on average approximately 92 claims for benefits under 42 U.S.C. 3796(k) annually, OJP estimates that it would need to seek additional evidence and review in fewer than 1 in 20 such claims, which is significantly fewer than it seeks under the previous rule.

This reduction in evidentiary development is also expected to result in cost savings for medical reviews as well as the costs associated with obtaining medical records for such reviews. For every claim that does not require independent medical review, OJP estimates a savings of $1,652, which represents the average cost to the program of obtaining certain medical opinions in claims for PSOB Program death benefits from 2009 through 2015. OJP also estimates a savings to the claimant of $603 for the cost of obtaining medical records (an average of 900 pages in the claims sampled). This estimate is based on the maximum fees permitted by law, which vary by state,[8] and the number of pages of medical records in claims for PSOB Program death benefits as determined in a random sampling of claims involving medical issues that require a claimant to provide such records. In addition, OJP believes that the streamlined criteria would increase the rate at which such claims are processed, however, it is difficult to quantify any additional cost savings resulting from such efficiencies.

In terms of benefit costs, OJP estimates that there will not be a significant increase in claims approved as compared to the previous regulatory criteria. Accordingly, the proposed rule does not significantly increase benefit costs. And, as these claims would be processed by existing staff, OJP would not incur additional administrative or personnel costs in processing these claims.

This proposed rule would impose no costs on state, local, or tribal governments, or on the private sector.

Although not an economically significant rulemaking under Executive Orders 12866 and 13563, The Office of Justice Programs has determined that this proposed rule is a "significant regulatory action" under section 3(f) of the Executive Order, and accordingly this rule has been reviewed by the Office of Management and Budget (OMB).

Executive Order 13132—Federalism

This proposed rule would not have substantial direct effects on the States, on the relationship between the federal government and the States, or on distribution of power and responsibilities among the various levels of government. The PSOB program statutes provide benefits to individuals and do not impose any special or unique requirements on States or localities. Therefore, in accordance with Executive Order No. 13132, it is determined that this proposed rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Executive Order 12988—Civil Justice Reform

This proposed rule meets the applicable standards set forth in sections 3(a) & (b)(2) of Executive Order No. 12988. Pursuant to section 3(b)(1)(I) of the Executive Order, nothing in this proposed rule or any previous rule (or in any administrative policy, directive, ruling, notice, guideline, guidance, or writing) directly relating to the Program that is the subject of this rule is intended to create any legal or procedural rights enforceable against the United States, except as the same may be contained within part 32 of title 28 of the Code of Federal Regulations.

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[6] The educational assistance benefit is payable only as a reimbursement to spouses and children of eligible public safety officers for eligible educational expenses such as tuition and fees. Further complicating matters related to estimation, eligible children have until they are 27 to complete qualifying coursework and spouses of eligible public safety officers have no age cutoff for completing qualifying coursework. In addition, claimants may submit claims for educational assistance up to six months before attending qualifying coursework, or at any time after a course has been completed. On occasion, the PSOB Program receives a single claim for all 45 months of benefits; however, the majority of claims are submitted on an academic-term by academic-term basis.

[7] Payments for PSOB educational assistance are calculated on the basis prescribed in 38 U.S.C. 3532 and are subject to increase based on increases in certain consumer price indexes as provided in 38 U.S.C. 3564.

[8] *See e.g.*, Joy Pritts, et al., *Privacy and Security Solutions for Interoperable Health Information Exchange: Report on State Medical Record Access Laws, https://www.healthit.gov/sites/default/files/290-05-0015-state-law-access-report-1.pdf;* Table A–5, *Overview of State Law: Maximum Fees Doctors and Hospitals May Charge Patients for Copies of Medical Records https://www.healthit.gov/sites/default/files/appa5-1.pdf.* (accessed June 16, 2016).

Regulatory Flexibility Act

The Office of Justice Programs hereby certifies that this proposed rule would not have a significant economic impact on a substantial number of small entities for the following reasons: This proposed rule addresses federal agency procedures; furthermore, this proposed rule would make amendments to clarify existing regulations and agency practice concerning public safety officers' death, disability, and education benefits and would do nothing to increase the financial burden on any small entities. Therefore, an analysis of the impact of this proposed rule on such entities is not required under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*).

Paperwork Reduction Act of 1995

This proposed rule would impose reporting or recordkeeping requirements under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*). The PRA requires certain actions before an agency can adopt or revise a collection of information, including publishing a summary of the collection of information and a brief description of the need for and proposed use of the information. 44 U.S.C. 3507.

The proposed rule includes paperwork requirements in three collections of information previously approved by OMB for the PSOB Program. OJP published in the **Federal Register** on January 11, 2016, a 60-day notice of "Agency Information Collection Activities" for each of the following forms: *Claim for Death Benefits* (OMB Number 1121–0024), *Report of Public Safety Officer's Death* (OMB Number 1121–0025), and *Public Safety Officers' Disability Benefits* (OMB Number 1121–0166). In calculating the burden associated with these forms/collections, OJP reviewed its previous burden estimates and updated these to reflect the time required for claimants to gather the many different documents necessary to establish eligibility for these benefits, *e.g.*, birth certificates, marriage certificates, divorce decrees (where applicable), public agency determinations as to death or disability benefits, medical records, etc. Information about the proposed collections is as follows:

Claim for Death Benefits—Overview of Information Collection

1. *Type of Information Collection:* Reinstatement with change of a previously approved collection.

2. *The Title of the Form/Collection:* Claim for Death Benefits.

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* Bureau of Justice Assistance. Office of Justice Programs, United States Department of Justice.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:*Primary: Eligible survivors of fallen public safety officers.

Abstract: BJA's Public Safety Officers' Benefits (PSOB) Office will use the Claim Form information to confirm the eligibility of applicants to receive Public Safety Officers' Death Benefits. Eligibility is dependent on several factors, including public safety officer status, an injury sustained in the line of duty, and the claimant status in the beneficiary hierarchy according to the PSOB Act. In addition, information to help the PSOB Office identify an individual is collected, such as Social Security numbers, telephone numbers, and email addresses. Changes to the claim form have been made in an effort to streamline the application process and eliminate requests for information that are either irrelevant or already being collected by other means.

OJP estimates that no more than 350 respondents will apply each year. Each application takes approximately 120 minutes to complete. OJP estimates that the total public burden (in hours) associated with the collection can be calculated as follows: Total Annual Reporting Burden: 350 x 120 minutes per application = 42,000 minutes/by 60 minutes per hour = 700 hours.

Public Safety Officer's Death—Overview of Information Collection

1. *Type of Information Collection:* Reinstatement with change of a previously approved collection.

2. *The Title of the Form/Collection:* Report of Public Safety Offices Death.

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* Bureau of Justice Assistance. Office of Justice Programs, United States Department of Justice.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Public safety agencies experiencing the death of a public safety officer according to the PSOB Act.

Abstract: BJA's Public Safety Officers' Benefits (PSOB) Office will use the Report of Public Safety Officer's Death Form information to confirm the eligibility of applicants to receive Public Safety Officers' Death Benefits. Eligibility is dependent on several factors, including public safety officer status, an injury sustained in the line of duty, and the claimant status in the beneficiary hierarchy according to the Act. In addition, information to help the PSOB Office identify an individual is collected, such as Social Security numbers, telephone numbers, and email addresses. Changes to the report form have been made in an effort to streamline the application process and eliminate requests for information that are either irrelevant or already being collected by other means.

OJP estimates that no more than 350 respondents will apply each year. Each application takes approximately 240 minutes to complete. OJP estimates that the total public burden (in hours) associated with the collection can be calculated as follows: Total Annual Reporting Burden: 350 × 240 minutes per application = 84,000 minutes/by 60 minutes per hour = 1400 hours.

Public Safety Officers' Disability Benefits—Overview of Information Collection

1. *Type of Information Collection:* Reinstatement with change of a previously approved collection.

2. *The Title of the Form/Collection:* Public Safety Officer's Disability Benefits.

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* Bureau of Justice Assistance. Office of Justice Programs, United States Department of Justice.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Public safety officers who were permanently and totally disabled in the line of duty.

Abstract: BJA's Public Safety Officers' Benefits (PSOB) Office will use the PSOB Disability Application information to confirm the eligibility of applicants to receive Public Safety Officers' Disability Benefits. Eligibility is dependent on several factors, including public safety officer status, injury sustained in the line of duty, and the total and permanent nature of the line-of-duty injury. In addition, information to help the PSOB Office identify individuals is collected, such as Social Security numbers, telephone numbers, and email addresses. Changes to the application form have been made in an effort to streamline the application process and eliminate requests for information that are either irrelevant or already being collected by other means.

OJP estimates that no more than 100 respondents will apply each year. Each application takes approximately 300 minutes to complete. OJP estimates that the total public burden (in hours) associated with the collection can be calculated as follows: Total Annual Reporting Burden: 100 × 300 minutes per application = 30,000 minutes/by 60 minutes per hour = 500 hours.

Unfunded Mandates Reform Act of 1995

This proposed rule would not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more in any one year, and it will not significantly or uniquely affect small governments. The PSOB program is a federal benefits program that provides benefits directly to qualifying individuals. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

List of Subjects in 28 CFR Part 32

Administrative practice and procedure, Claims, Disability benefits, Education, Emergency medical services, Firefighters, Law enforcement officers, Reporting and recordkeeping requirements, Rescue squad.

Accordingly, for the reasons set forth in the preamble, part 32 of chapter I of Title 28 of the Code of Federal Regulations is proposed to be amended as follows:

PART 32—PUBLIC SAFETY OFFICERS' DEATH, DISABILITY, AND EDUCATIONAL ASSISTANCE BENEFITS CLAIMS

■ 1. The authority citation for 28 CFR part 32 continues to read as follows:

Authority: 42 U.S.C. ch. 46, subch. XII; 42 U.S.C. 3782(a), 3787, 3788, 3791(a), 3793(a)(4) & (b), 3795a, 3796c–1, 3796c–2; sec. 1601, title XI, Pub. L. 90–351, 82 Stat. 239; secs. 4 through 6, Pub. L. 94–430, 90 Stat. 1348; secs. 1 and 2, Pub. L. 107–37, 115 Stat. 219.

■ 2. Amend § 32.3 as follows:

■ a. Amend the definition of *Act* by removing "and Apr. 5, 2006 (designated beneficiaries))" and adding in its place "Apr. 5, 2006 (designated beneficiaries); and Jan. 2, 2013)".

■ b. Add definitions of *List of WTC-related health conditions* and *Physical harm* in alphabetical order to read as follows:

§ 32.3 Definitions.

* * * * *

List of WTC-related health conditions means the list of *health* conditions (other than a mental-health condition) listed—

(1) At 42 U.S.C. 300mm–22(a)(3); or

(2) On the List of WTC-Related Health Conditions in 42 CFR part 88.

* * * * *

Physical harm means physical harm as defined at 28 CFR 104.2(c).

* * * * *

■ 3. Amend § 32.5 by adding paragraph (j) to read as follows:

§ 32.5 Evidence.

* * * * *

(j) Physical harm suffered by a public safety officer as a direct and proximate result of a condition on the List of WTC-Related Health Conditions shall be understood to be a line-of-duty injury if, as determined by the PSOB determining official, and pursuant to the standards governing the World Trade Center Health Program's certification of injuries as covered by the program, such officer's exposure to airborne toxins, any other hazards, and any other adverse conditions resulting from the September 11, 2001, terrorist attacks is substantially likely to have been a significant factor in aggravating, contributing to, or causing the illness or health condition.

■ 4. Amend § 32.6 by adding paragraph (f) to read as follows:

§ 32.6 Payment and repayment.

* * * * *

(f)(1) If compensation under the September 11th Victim Compensation Fund of 2001 (49 U.S.C. 40101 note)) has been paid with respect to an injury, the total amount payable under subpart B or C of this part, with respect to the same injury, shall be reduced by the amount of such payment of compensation.

(2) Nothing in paragraph (f)(1) of this section, or in the Act, at 42 U.S.C. 3796(f)(3), shall be understood to preclude payment under this part before the final payment of compensation under such Fund.

(3) Nothing in the Act, at 42 U.S.C. 3796(f)(3), shall be understood to require reduction of any amount payable under subpart D of this part.

■ 5. Amend § 32.13 as follows:

■ a. Add definitions of *Something other than the mere presence of cardiovascular disease risk factors* and *Unrelated* in alphabetical order.

■ b. Remove the definitions of *Competent medical evidence to the contrary, Excessive consumption of alcohol, Extrinsic circumstances, Risky behavior,* and *Undertaking of treatment.*

The additions read as follows:

§ 32.13 Definitions.

* * * * *

Something other than the mere presence of cardiovascular disease risk factors means—

(1) Ingestion of controlled substances included on Schedule I of the drug control and enforcement laws (see 21 U.S.C. 812(a)); or

(2) Abuse of controlled substances included on Schedule II, III, IV, or V of the drug control and enforcement laws (see 21 U.S.C. 812(a)).

* * * * *

Unrelated—A public safety officer's heart attack, stroke, or vascular rupture is unrelated to the officer's engagement in a situation or participation in a training exercise, as described in 42 U.S.C. 3796(k)(1), when an independent event or occurrence significantly contributes in bringing about the officer's heart attack, stroke, or vascular rupture.

§ 32.14 [Amended]

■ 6. In § 32.14, remove paragraph (c).

■ 7. In § 32.33, the definition of *Eligible public safety officer* is revised to read as follows:

§ 32.33 Definitions.

* * * * *

Eligible public safety officer means a public safety officer—

(1) With respect to whose death, benefits under subpart B of this part properly—

(i) Have been paid; or

(ii) Would have been paid but for operation of the Act, at 42 U.S.C. 3796(f); or

(2) With respect to whose disability, benefits under subpart C of this part properly—

(i) Have been paid; or

(ii) Would have been paid, but for operation of—

(A) Paragraph (b)(1) of § 32.6; or

(B) The Act, at 42 U.S.C. 3796(f).

* * * * *

Dated: June 30, 2016.

Karol V. Mason,

Assistant Attorney General.

[FR Doc. 2016–16086 Filed 7–14–16; 8:45 am]

BILLING CODE P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 110

[Docket Number USCG–2016–0110]

RIN 1625–AA01

Anchorage Grounds; Delaware Bay and River, Philadelphia, PA

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to amend the anchorage regulations for Delaware Bay and River. The Coast Guard conducted a review of the Delaware Bay and River anchorage

grounds to support increased traffic and vessel size. The proposed changes to this regulation would eliminate unusable anchorage grounds and provide additional usable grounds to support current and future port demands and enhance the overall navigation safety of this critical component of the maritime transportation system. We invite your comments on this proposed rulemaking.

DATES: Comments and related material must be received by the Coast Guard on or before August 15, 2016.

ADDRESSES: You may submit comments identified by docket number USCG–2016–0110 using the Federal eRulemaking Portal at *http://www.regulations.gov.* See the "Public Participation and Request for Comments" portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions about this rulemaking, call or email Lieutenant Brennan Dougherty, U.S. Coast Guard, Sector Delaware Bay, Chief Waterways Management Division, telephone (215) 271–4851, email *Brennan.P.Dougherty@uscg.mil* or Lieutenant Commander Tiffany Johnson, U.S. Coast Guard, Fifth Coast Guard District, Waterways Management Branch, telephone (757) 398–6516, email *Tiffany.A.Johnson@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR	Code of Federal Regulations
DHS	Department of Homeland Security
FR	Federal Register
NPRM	Notice of proposed rulemaking
§	Section
U.S.C.	United States Code
COTP	Captain of the Port

II. Background, Purpose, and Legal Basis

The Delaware Bay and River anchorage grounds are largely used by commercial vessel traffic. General regulations covering the anchorage of vessels in the port are set out in 33 CFR 110.157. In 1992, the Delaware River Main Channel Deepening project was authorized for construction by Public Law 102–580, Section 101 (6) of the Water Resources Development Act (WRDA) 1992; modified by Public Law 106–53, Section 308 of WRDA 1999 and further modified by Public Law 106–541, Section 306 of WRDA 2000. This project includes deepening the existing Delaware River Federal Navigation Channel from 40 to 45 feet from Philadelphia, Pennsylvania, and Camden, New Jersey to the mouth of the Delaware Bay. The Army Corps of Engineers (USACE) along with non-Federal sponsor, the Philadelphia Regional Port Authority (PRPA), commenced dredging for this project in 2010. This project, once completed, will allow for deeper draft vessels within the port and increase overall traffic, and anchorage usage. Due to this anticipated increase in marine traffic a review of the current Delaware Bay and River anchorage grounds was conducted by the Waterways Management Division Sector Delaware Bay, Philadelphia, PA in coordination with the Mariners Advisory Committee (MAC). Upon review it was found that multiple anchorage grounds in 33 CFR 110.157 were unusable for some larger vessels due to lack of depth needed to safely anchor. Other anchorage grounds are unusable because they spanned underneath bridges where it would be impractical for vessels to anchor, and posed an increased and unnecessary safety risk of bridge allision. The proposed changes to the Delaware Bay and River anchorages would eliminate unusable anchorage grounds and maximize usable anchorage grounds within the anchorage boundaries while continuing to safely support current and future port demands. The Coast Guard proposes this rulemaking under authority in 33 U.S.C. 1231.

III. Discussion of Proposed Rule

The following changes are being proposed for seven Delaware Bay and River anchorage grounds.

Anchorage 1 Bombay off Hook Point, found in 33 CFR 110.157 (a)(2), currently has portions of the anchorage which intermittently experiences a water depth of 2 feet, which is unsafe for vessels to transit or anchor. The proposed changes would reduce the width of the anchorage to approximately 1,109 yards while extending the length to approximately 9,802 yards, thereby allowing more room for safe usable space within the anchorage.

Anchorage 3 southeast of Reedy Point, found in 33 CFR 110.157(a)(4), currently has portions of the anchorage in the navigational channel. Furthermore, the northern portion of the anchorage, in relation to the entrance to the Chesapeake and Delaware Canal, poses an unnecessary risk of vessel collisions due to the proximity of vessels transiting to and from the canal. The proposed changes would move this anchorage 1,573 yards south of the Chesapeake and Delaware Canal 2 light, bounding the east side of the anchorage along the west side of Reedy Island Range, and extend the anchorage south to the southern end of Reed Island Bar. These changes would eliminate portions of the anchorage that are in the navigational channel and increase the anchorage grounds southward.

Anchorage 6 off Deepwater Point, found in 33 CFR 110.157 (a)(7), currently has the southern portion of the anchorage approximately 480 yards north from the Delaware Memorial Bridge, this proximity creates an unnecessary risk of a bridge allision. To mitigate this risk, the proposed changes would relocate the southern boundary of the anchorage to approximately 701 yards north of the Delaware Memorial Bridge and extend the northern portion of the anchorage where it would end opposite the channel from the entrance of the Christina River.

Anchorage 8 off Thompson Point, found in 33 CFR 110.157(a)(9), currently has portions of the anchorage in less than 9 feet of water, causing an unnecessary safety risk to vessels attempting to transit or anchor. The proposed changes would increase usable anchorage grounds within the anchorage by reducing the width of the anchorage to approximately 231 yards and extending the northern end of the anchorage to the edge of Crab Point.

Anchorage 11 at Gloucester, found in 33 CFR 110.157(a)(12), currently has the northern portion of the anchorage approximately 71 yards south of the Walt Whitman Bridge. This proximity creates an unnecessary risk of a bridge allision. The proposed changes would increase the distance of the northern portion of the anchorage to 254 yards from the Walt Whitman Bridge, reducing the risk of a bridge allision for vessels in the anchorage.

Anchorage 12 between Gloucester and Camden, found in 33 CFR 110.157(a)(13), currently begins south of the Walt Whitman Bridge, bordering the northern line of Anchorage 11 traveling north to the southern boundary of Anchorage 13 at Camden, NJ. Anchorages 12 and 13 each span a bridge where anchoring a vessel is impractical and creates an unnecessary risk of bridge allision. The proposed changes would address this issue by relocating the south end of Anchorage 12 to begin 232 yards north of the Walt Whitman Bridge and relocating the northern boundary to approximately 155 yards south of the Benjamin Franklin Bridge. This would eliminate any anchorage grounds underneath the Walt Whitman Bridge and Benjamin Franklin Bridge, mitigating the unnecessary risk of a bridge allision.

Anchorage 13, found in 33 CFR 110.157(a)(14), currently begins on the east side of the channel adjoining and on the upstream side of Anchorage 12, to Cooper Point, Camden. Anchorages 12 and 13 each span a bridge where anchoring a vessel is impractical and creates an unnecessary risk of bridge allision. The proposed changes above would move the south end of Anchorage 13 to begin approximately 190 yards north of the Benjamin Franklin Bridge. Anchorage 13's northern boundary would remain the same, terminating in the vicinity of Coopers Point, Camden. This would eliminate any anchorage grounds underneath Benjamin Franklin Bridge, mitigating the unnecessary risk of a bridge allision.

IV. Regulatory Analyses

We developed this proposed rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive Orders.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This NPRM has not been designated a "significant regulatory action," under Executive Order 12866. Accordingly, the NPRM has not been reviewed by the Office of Management and Budget.

This proposed rule is not a significant regulatory action because it would not interfere with existing maritime activity on the Delaware River. Rather, it would enhance navigational safety along the Delaware River by providing safer locations for vessels to anchor, improving navigation safety near bridges and reducing the potential for disruption to maritime traffic by anchored vessels potentially within the federal channel. Vessels may navigate in, around, and through the modified anchorages.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term "small entities" comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this proposed rule would not have a significant economic impact on a substantial number of small entities.

The proposed rule would affect owners and operators of vessels wishing to anchor in the Delaware Bay and River anchorages. Boundaries of some of the current anchorages would be modified, reduced, or increased depending on the water depth and relation of the anchorage to bridges along the Delaware Bay and River. The impact of the proposed rule changes would be minimal because the changes increase usable anchorage grounds and enable vessels to safely anchor in the anchorage boundaries.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this proposed rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section. The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

C. Collection of Information

This proposed rule would not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this proposed rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this proposed rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it would not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. If you believe this proposed rule has implications for federalism or Indian tribes, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this proposed rule would not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this proposed rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have made a preliminary determination that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This proposed rule involves directly with establishing, disestablishing, and modifying anchorage grounds. Normally such actions are categorically excluded from further review under paragraph 34(f) of Figure 2–1 of Commandant Instruction M16475.lD. A preliminary environmental analysis checklist and Categorical Exclusion Determination are available in the docket where indicated under **ADDRESSES**. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

V. Public Participation and Request for Comments

We view public participation as essential to effective rulemaking, and will consider all comments and material received during the comment period. Your comment can help shape the outcome of this rulemaking. If you submit a comment, please include the docket number for this rulemaking, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation.

We encourage you to submit comments through the Federal eRulemaking Portal at *http://www.regulations.gov.* If your material cannot be submitted using *http://www.regulations.gov,* contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

We accept anonymous comments. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information you have provided. For more about privacy and the docket, you may review a Privacy Act notice regarding the Federal Docket Management System in the March 24, 2005, issue of the **Federal Register** (70 FR 15086).

Documents mentioned in this NPRM as being available in the docket, and all public comments, will be in our online docket at *http://www.regulations.gov* and can be viewed by following that Web site's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted or a final rule is published.

List of Subjects in 33 CFR Part 110

Anchorage grounds.

For the reasons discussed in the preamble, the Coast Guard proposes to amend 33 CFR part 110 as follows:

PART 110—ANCHORAGE REGULATIONS

■ 1. The authority citation for part 110 continues to read as follows:

Authority: 33 U.S.C. 471, 1221 through 1236, 2071; 33 CFR 1.05–1; Department of Homeland Security Delegation No. 0170.1.

■ 2. Amend § 110.157 by revising paragraphs (a)(2), (4), (7), (9), and (12) through (14) to read as follows:

§ 110.157 Delaware Bay and River.

(a) * * *

(2) *Anchorage 1 off Bombay Hook Point.* On the southwest side of the channel along Liston Range, bounded as follows: Beginning at a point (approximately latitude 39°17′14″ N., longitude 75°22′21″ W.) bearing 170° from Ship John Shoal Light, 380 yards southwest of the southwest edge of the channel along Liston Range; thence 231°, 1,000 yards; thence 319°, 9,800 yards; thence 049°, 1,000 yards; and thence 139°, 9,800 yards, back to the beginning point. These coordinates are based on the World Geodetic System 1984 (WGS 84) horizontal datum reference.

* * * * *

(4) *Anchorage 3 southeast of Reedy Point.* Southeast of the entrance to the Chesapeake and Delaware Canal at Reedy Point, bounded as follows: Beginning at a point (approximately latitude 39°33′09″ N. and longitude 75°32′38″ W.), bearing 120°, 1,573 yards southeast from Chesapeake and Delaware Canal 2 Light, bounded on the east by the west edge of the channel along Reedy Island Range, south to a point (approximately latitude 39°31′29″ N. and longitude 75°33′01″ W.), thence 286°, 406 yards, thence 008°, 1,460 yards, continuing north by a line running from the last point to (approximately latitude 39°33′09″ N. and longitude 75°33′10″ W.), 1,817 yards, and thence 90°, 840 yards, to the point of beginning. These coordinates are based on the World Geodetic System 1984 (WGS 84) horizontal datum reference.

* * * * *

(7) *Anchorage 6 off Deepwater Point.* East of the entrance to Christina River, bounded as follows: Beginning at latitude 39°43′00″ N., longitude 75°30′20″ W.; thence 106°, 966 yards; thence 214°, 1,882 yards; thence 203°, 828 yards; thence 182°, 232 yards; thence 283°, 335 yards; and thence 015°, 2,858 yards, along the east side of the Cherry Island Range, to the point of beginning. Vessels must not cast anchor in the cable area at the lower end of this anchorage except in case of emergency. These coordinates are based on the World Geodetic System 1984 (WGS 84) horizontal datum reference.

* * * * *

(9) *Anchorage 8 off Thompson Point.* On the south side of the channel along Tinicum Range, between Thompson Point and the east side of Crab Point, bounded as follows: Beginning at a point on the south edge of the channel along Tinicum Range at longitude 75°18′23″ W.; thence easterly along the edge of the channel to longitude 75°17′41″ W.; thence 185°, 220 yards; thence 272°, 1,079 yards; thence 001°, 192 yards, to the point of beginning. These coordinates are based on the World Geodetic System 1984 (WGS 84) horizontal datum reference.

* * * * *

(12) *Anchorage 11 at Gloucester.* East of the channel south of the Walt Whitman Bridge at Gloucester, bounded as follows: Beginning at a point latitude 39°54′11″ N., longitude 75°07′45″ W.; thence bearing 101°, 85 yards, thence 177°, 275 yards to a point latitude 39°54′03″ N., longitude 75°07′41″ W., along the New Jersey shore, thence 200°, 1,179 yards; thence 216°, 875 yards to a point at latitude 39°53′10″ N., longitude 75°08′17″ W., thence northeasterly bearing 026°, 1,006 yards, and thence 018°, 1,203 yards to the point of beginning. The area between Pier 124 S and 122 S, along the west side of the Delaware River, is restricted to facilitate vessel movements. The areas adjacent to working piers are restricted to facilitate the movement of vessels to and from these piers. Should the anchorage become so congested that vessels are compelled to anchor in these restricted areas, they must move immediately when another berth is available. These coordinates are based on the World Geodetic System 1984 (WGS 84) horizontal datum reference.

(13) *Anchorage 12 between Gloucester and Camden.* East of the channel beginning north of the Walt Whitman Bridge at Gloucester and ending south of the Benjamin Franklin Bridge at Camden, bounded as follows: Beginning at a point at latitude 39°54′26″ N., longitude 75°07′41″ W., bounded on the west by a line perpendicular to the channel, 210 yards from the east edge of the channel north, 5,536 yards, thence bearing 098°, 178 yards, thence 193°, 437 yards, thence 185°, 546 yards, thence 179°, 1,107 yards, thence 168°, 964 yards, thence 161°, 1,749 yards, thence 182°, 401 yards, thence 195°, 305 yards, and thence 276°, 132 yards to the point of beginning. The area between No. 2 Broadway pier and No. 1 Broadway pier is restricted to facilitate vessel movements. The areas adjacent to working piers are restricted to facilitate the movement of vessels to and from these piers. Should the anchorage become so congested that vessels are compelled to anchor in these restricted areas, they must move immediately when another berth is available. These coordinates are based on the World Geodetic System 1984 (WGS 84) horizontal datum reference.

(14) *Anchorage 13 at Camden.* East of the channel, North of the Benjamin Franklin Bridge to Cooper Point, Camden, bounded as follows: Beginning at a point latitude 39° 57′17″, longitude 75°07′58″, thence bearing 16°, 209 yards, thence 27°, 368 yards, thence 46°, 355 yards, thence 139°, 200 yards, thence 221°, 604 yards, thence 199°, 222 yards, and thence 287°, 147 yards to the point of beginning. These coordinates are based on the World Geodetic System 1984 (WGS 84) horizontal datum reference.

* * * * *

Dated: June 20, 2016.

Meredith L. Austin,

Admiral, U.S. Coast Guard, Commander, Fifth Coast Guard District.

[FR Doc. 2016–16744 Filed 7–14–16; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 131

[EPA–HQ–OW–2015–0392; FRL–9946–01–OW]

RIN 2040–AF61

Water Quality Standards; Establishment of Revised Numeric Criteria for Selenium for the San Francisco Bay and Delta, State of California

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to revise the current federal Clean Water Act selenium water quality criteria applicable to the San Francisco Bay and Delta to ensure that the criteria are set at levels that protect aquatic life and aquatic-dependent wildlife, including federally listed threatened and endangered species. The San Francisco Bay and Delta ecosystem is at risk due to environmental degradation, including impacts from elevated levels of selenium, and state and federal actions are underway to restore the waterway. Scientific evidence indicates that elevated selenium levels can contribute to the decline of fish and aquatic-dependent birds. EPA promulgated the San Francisco Bay and Delta's existing selenium criteria in 1992 as part of the National Toxics Rule, using EPA's recommended aquatic life criteria values at the time. However, the latest science on selenium fate and bioaccumulation indicates that the existing criteria are not protective of aquatic life and aquatic-dependent wildlife in the San Francisco Bay and Delta. Therefore, EPA is proposing to revise the existing selenium criteria, taking into account available science, legal requirements, and EPA policies and guidance. EPA's proposal will address the Administrator's determination—described in this preamble—that EPA's previously promulgated water quality criteria are not adequate to protect the designated uses for these waters.

DATES: Comments must be received on or before September 13, 2016.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OW–2015–0392, at *http://www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov.* EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

Two public hearings will be held on Tuesday, August 23, 2016, one at 9:00 a.m. and one at 2:00 p.m., at EPA Region 9, 75 Hawthorne Street, San Francisco, CA 94105. Additionally, EPA will offer a virtual public hearing on the proposed rule via the internet on Monday evening, August 22, 2016 from 6:00 p.m. to 8:00 p.m. For details on these public hearings, as well as registration information, please visit: *https://epa.gov/wqs-tech/water-quality-standards-establishment-revised-numeric-criteria-selenium-san-francisco-bay.*

FOR FURTHER INFORMATION CONTACT: Erica Fleisig, Office of Water, Standards and Health Protection Division (4305T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue NW., Washington, DC 20460; telephone number: (202) 566–1057; email address: *Fleisig.Erica@EPA.gov;* or Diane E. Fleck, P.E., Esq., Water Division (WTR–2–1), U.S. Environmental Protection Agency Region 9, 75 Hawthorne Street, San Francisco, CA 94105; telephone number: (415) 972–3527; email address: *Fleck.Diane@EPA.gov.*

SUPPLEMENTARY INFORMATION: This proposed rule is organized as follows:

I. General Information
II. Background
  A. CWA and EPA Regulations
  B. National Toxics Rule
  C. California Toxics Rule
  D. State of California Actions
  E. Applicability of EPA Promulgated Water Quality Standards When Final
  F. Selenium Chemistry and Biology
III. Rationale and Approach
  A. Necessity
  B. Administrator's Determination of Necessity
  C. Approach
  D. Proposed Criteria
IV. Implementation and Alternative Regulatory Approaches
V. Endangered Species Act
VI. Economic Analysis
  A. Identifying Affected Entities
  B. Method for Estimating Costs
  C. Results
VII. Statutory and Executive Orders
  A. Executive Order 12866 (Regulatory Planning and Review) and Executive Order 13563 (Improving Regulation and Regulatory Review)
  B. Paperwork Reduction Act (PRA)
  C. Regulatory Flexibility Act (RFA)
  D. Unfunded Mandates Reform Act (UMRA)
  E. Executive Order 13132 (Federalism)
  F. Executive Order 13175 (Consultation and Coordination With Indian Tribal Governments)
  G. Executive Order 13045 (Protection of Children From Environmental Health and Safety Risks)
  H. Executive Oder 13211 (Actions That Significantly Affect Energy Supply, Distribution, or Use)
  I. National Technology Transfer and Advancement Act of 1995
  J. Executive Order 12898 (Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations)

I. General Information

Applicability: Entities such as industries, stormwater management districts, or publicly owned treatment works (POTWs) that directly or indirectly discharge selenium to the San Francisco Bay and Delta could be indirectly affected by this rulemaking because federal water quality standards (WQS) promulgated by EPA would be applicable to Clean Water Act (CWA) regulatory programs, such as National Pollutant Discharge Elimination System (NPDES) permitting. Citizens concerned with water quality in California could also be interested in this rulemaking. Categories and entities that could be affected include the following:

Category	Examples of potentially affected entities
Industry	Industries discharging pollutants to the San Francisco Bay and Delta.

Category	Examples of potentially affected entities
Municipalities	Publicly owned treatment works or other facilities discharging pollutants to the San Francisco Bay and Delta.
Stormwater Management Districts	Entities responsible for managing stormwater runoff in the San Francisco Bay and Delta.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities that could be indirectly affected by this action. Any parties or entities who depend upon or contribute to the water quality of the San Francisco Bay and Delta could be affected by this proposed rule. To determine whether your facility or activities could be affected by this action, you should carefully examine this proposed rule. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

II. Background

A. CWA and EPA Regulations

CWA section 101(a)(2) (33 U.S.C. 1251(a)(2)) establishes a national goal, wherever attainable, of "water quality which provides for the protection and propagation of fish, shellfish, and wildlife and provides for recreation in and on the water . . ." In this proposal, the relevant goals are the protection and propagation of fish, shellfish, and wildlife.

CWA section 303(c) (33 U.S.C. 1313(c)) directs states to adopt WQS for their waters subject to the CWA. CWA section 303(c)(2)(A) and EPA's implementing regulations at 40 CFR part 131 require, among other things, that a state's WQS specify appropriate designated uses of the waters and water quality criteria that protect those uses. EPA's regulations at 40 CFR 131.11(a)(1) provide that "[s]uch criteria must be based on sound scientific rationale and must contain sufficient parameters or constituents to protect the designated use." For waters with multiple use designations, the criteria must support the most sensitive use (40 CFR 131.11(a)(1)). In addition, 40 CFR 131.10(b) provides that "[i]n designating uses of a water body and the appropriate criteria for those uses, the [s]tate shall take into consideration the water quality standards of downstream waters and shall ensure that its water quality standards provide for the attainment and maintenance of the water quality standards of downstream waters."

States are required to review applicable WQS at least once every three years and, if appropriate, revise or adopt new standards (CWA section 303(c)(1)). Any new or revised WQS must be submitted to EPA for review and approval or disapproval (CWA section 303(c)(2)(A) and (c)(3)). Under CWA section 303(c)(4)(B), the Administrator is authorized to determine, even in the absence of a state submission, that a new or revised standard is needed to meet CWA requirements.

Under CWA section 304(a), EPA periodically publishes criteria recommendations for states to consider when adopting water quality criteria for particular pollutants to meet the CWA section 101(a)(2) goals. In establishing numeric criteria, states should adopt water quality criteria based on EPA's CWA section 304(a) criteria, section 304(a) criteria modified to reflect site-specific conditions, or other scientifically defensible methods (40 CFR 131.11(b)(1)). CWA section 303(c)(2)(B) requires states to adopt numeric criteria for all toxic pollutants listed pursuant to CWA section 307(a)(1) for which EPA has published 304(a) criteria, as necessary to support the states' designated uses.

B. National Toxics Rule

On December 22, 1992, EPA promulgated *Water Quality Standards; Establishment of Numeric Criteria for Priority Toxic Pollutants; States' Compliance* at 57 FR 60848 (hereafter referred to as the National Toxics Rule or NTR).[1] The NTR established chemical-specific numeric criteria for priority toxic pollutants for states that EPA had determined were not in compliance with the requirements of CWA section 303(c)(2)(B). The NTR included selenium water quality criteria for the protection of aquatic life in the San Francisco Bay and Delta. On May 4, 1995, EPA issued a stay of the criteria for metals in the NTR and immediately promulgated revised criteria for metals in the NTR in the *Stay of Federal Water Quality Criteria for Metals* at 60 FR 22227 and *Water Quality Standards; Establishment of Numeric Criteria for Priority Toxic Pollutants; States' Compliance—Revision of Metals Criteria,* at 60 FR 22229.[2] The 1995 Stay and Revision did not change the selenium water quality criteria for the San Francisco Bay and Delta. These criteria are currently applicable in the Bay and Delta, and consist of a chronic criterion of 5 micrograms per liter (µg/L), and an acute criterion of 20 µg/L. Both criteria are expressed in the total recoverable form of selenium.

The currently applicable selenium criteria for the protection of aquatic life in the San Francisco Bay and Delta were based on EPA's CWA section 304(a) recommended criteria values at the time that EPA promulgated the criteria in the NTR. These recommendations are documented in EPA's *Ambient Water Quality Criteria for Selenium—1987,* Office of Water, EPA–440/5–87–008, September, 1987.

EPA derived the 1987 freshwater aquatic life recommended criteria values for selenium from observed impacts on fish populations at a contaminated lake, Belews Lake, in North Carolina. The lake, a cooling water reservoir, had been affected by selenium loads from a coal-fired power plant. Since aquatic life was exposed to selenium from both the water column and diet, the criteria reflect both types of exposure in Belews Lake. EPA derived the 1987 saltwater aquatic life recommended criteria values for selenium using data from lab studies. EPA calculated the criteria in accordance with EPA's *Guidelines for Deriving Numerical National Water Quality Criteria for the Protection of Aquatic Organisms and Their Uses,* Office of Research and Development, 1985. The 1987 recommended freshwater criteria values for total recoverable selenium are 5 µg/L (chronic) and 20 µg/L (acute), and the saltwater criteria values for total recoverable selenium are 71 µg/L (chronic) and 300 µg/L (acute).

In the NTR, EPA promulgated selenium criteria for the San Francisco

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[1] The NTR is codified at 40 CFR 131.36.

[2] The purpose of the 1995 amendment was, in general, to replace aquatic life total recoverable metals criteria with dissolved metals criteria to reflect a revised EPA policy that dissolved metals criteria better represent the biologically available fraction of water borne metals to aquatic organisms. Although selenium was included in the analysis for the revised policy, the 1995 amendment did not include a freshwater conversion factor for selenium, and thus, the aquatic life freshwater selenium criteria in the NTR remain in the total recoverable form. The EPA policy memorandum, *Office of Water Policy and Technical Guidance on Interpretation and Implementation of Aquatic Life Metals Criteria,* by Martha G. Prothro on October 1, 1993, states that selenium is a "bioaccumulative chemical and [it is] not appropriate to adjust to percent dissolved" for freshwater selenium criteria (see policy memorandum, Attachment 2, page 5).

Bay and Delta based on the 1987 freshwater recommended criteria values for selenium, even though the San Francisco Bay and Delta are marine and estuarine waters. EPA used the more stringent freshwater values because of a concern that the saltwater criteria were not sufficiently protective ''based on substantial evidence that there are high levels of selenium bioaccumulation in San Francisco Bay and the saltwater criteria fail to account for food chain effects'' and ''utilization of the saltwater criteria for selenium in the San Francisco Bay/Delta would be inappropriate.'' (57 FR 60898).

Since then, EPA has taken steps to revise the 1987 CWA 304(a) recommended criteria for selenium to better account for bioaccumulation through the food chain in different ecosystems. EPA recently published a revised CWA 304(a) freshwater recommended criterion for selenium: *Final Aquatic Life Ambient Water Quality Criterion for Selenium—Freshwater 2016,* US EPA, Office of Water, EPA 822–R–16–006, June, 2016. EPA considered the methodology and information used to derive the revised CWA 304(a) recommended selenium criterion, along with additional information specific to the San Francisco Bay and Delta, in developing the revised selenium criteria values for the San Francisco Bay and Delta in this proposed rule.

C. California Toxics Rule

On May 18, 2000, EPA promulgated *Water Quality Standards; Establishment of Numeric Criteria for Priority Toxic Pollutants for the State of California* at 65 FR 31681 (hereafter referred to as the California Toxics Rule or CTR).[3] The CTR established numeric water quality criteria for priority toxic pollutants for inland surface waters and enclosed bays and estuaries within California. EPA promulgated the CTR after California rescinded its water quality control plans containing pollutant objectives (criteria). The criteria that EPA previously promulgated for California in the NTR,[4] together with the criteria promulgated in the CTR and California's designated uses and anti-degradation provisions, set water quality standards for priority toxic pollutants for inland surface waters and enclosed bays and estuaries in California.

As required by section 7 of the Endangered Species Act (ESA) (16 U.S.C. 1531 *et seq.*), EPA consulted with the U.S. Fish and Wildlife Service (FWS) and the U.S. National Marine Fisheries Service (NMFS) (collectively, the Services) concerning EPA's rulemaking actions for California. EPA initiated consultation in 1994, and in March 2000, the Services issued a final Joint Biological Opinion. The final Joint Biological Opinion requested that EPA revise its 1987 recommended criteria values for selenium to ensure the protection of species listed as threatened or endangered, and later update the criteria for California consistent with the revised recommendations. In response, EPA reserved the acute freshwater selenium criterion from the final May 2000 CTR.

In September 2002, EPA, the Services, the U.S. Geological Survey (USGS), and the State of California met to discuss the development of revised selenium water quality criteria and recommended that California-specific selenium water quality criteria be developed as wildlife criteria. The agencies agreed that criteria should first be developed to protect aquatic life and aquatic-dependent wildlife using the Luoma-Presser (USGS) bioaccumulation model[5] for the San Francisco Bay and Delta based on the necessity for more stringent criteria in the estuary, and to subsequently develop criteria for the rest of California using appropriate methods.

Starting in 2003, EPA and the Services provided assistance to the USGS to model selenium fate and biological uptake in the San Francisco Bay and Delta using the USGS bioaccumulation model. USGS completed its report, entitled *Ecosystem-Scale Selenium Modeling in Support of Fish and Wildlife Criteria Development for the San Francisco Bay-Delta Estuary, California, Administrative Report* (the USGS Report), and submitted it to EPA in December 2010. USGS used site-specific data from various sources and species-specific data from the FWS. EPA analyzed the USGS Report and data from the FWS and other relevant reports to develop the selenium criteria for the San Francisco Bay and Delta in this proposed rule.

In 2013, two organizations filed a legal complaint against EPA, based in part on the fact that work on updating the reserved acute freshwater selenium criterion from the 2000 CTR had not yet been completed while EPA had previously determined, in the proposed CTR, that the criterion was among those necessary to implement section 303(c)(2)(B) of the CWA (62 FR 42160, August 5, 1997). EPA ultimately consented to a court-ordered resolution of these claims.[6] Under the terms of the court order, EPA committed to developing updated selenium criteria for the California waters covered by the original CTR. However, this proposed rule relates to a different set of selenium criteria: Those selenium criteria that EPA previously proposed and finalized for the San Francisco Bay and Delta in the NTR. Since EPA has chosen to prioritize the development of this latter set of selenium criteria, EPA expects to defer proposing the remaining selenium criteria for the rest of California until no later than November 30, 2018, pursuant to the terms of the court-ordered resolution.

D. State of California Actions

The State of California has nine Regional Water Quality Control Boards (Regional Boards), each located in and overseeing different areas of the state. The State Water Resources Control Board (SWRCB) in Sacramento oversees the actions of the nine Regional Boards and periodically establishes policy and standards for consistency across the Regional Boards. The San Francisco Bay Regional Water Quality Control Board (SFRWQCB) and the Central Valley Regional Water Quality Control Board (CVRWQCB) oversee different parts of the Bay and Delta. The SFRWQCB oversees all parts of the San Francisco Bay including the South San Francisco Bay, Lower San Francisco Bay, Central San Francisco Bay, San Pablo Bay, Carquinez Strait and Suisun Bay, and a small portion of the western side of Sacramento-San Joaquin Delta. The CVRWQCB oversees the remaining areas of the Delta which include the confluences of the Sacramento and the San Joaquin Rivers. Each Regional Board has a regional water quality control plan (Basin Plan) that sets forth the beneficial (designated) uses for the waterbodies it oversees. Once EPA finalizes the proposed criteria, each Regional Board will implement the criteria in its WQS programs for the waters it oversees.

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[3] The CTR is codified at 40 CFR 131.38.

[4] The CTR Criteria Table at 40 CFR 131.38(b)(1) includes all water quality criteria previously promulgated in the NTR, so that readers can find all federally promulgated water quality criteria for California in one place. All criteria previously promulgated in the NTR are footnoted as such in the CTR.

[5] The model developed by Theresa Presser and Sam Luoma is the selenium ecosystem bioaccumulation model first presented in *Forecasting Selenium Discharges to the San Francisco Bay-Delta Estuary: Ecological Effects of a Proposed San Luis Drain Extension, Open File Report 00–416,* Samuel N. Luoma and Theresa S. Presser, 2000, U.S. Geological Survey, Menlo Park, California. This report was revised and superseded in 2006 by *Professional Paper 1646,* Theresa S. Presser and Samuel N. Luoma, U.S. Geological Survey, Reston, Virginia. A detailed explanation of the model is contained in *A Methodology for Ecosystem-Scale Modeling of Selenium,* T.S. Presser and S.N. Luoma, 2010, Integrated Environmental Assessment and Management, Volume 6, Number 4.

[6] *Our Children's Earth Foundation and Ecological Rights Foundation* v. *U.S. Environmental Protection Agency, et al.,* 13–cv–2857 (N.D. Cal, August 22, 2014).

In 1978, the SWRCB adopted a comprehensive plan for the Bay and Delta estuary: *The Water Quality Control Plan for the San Francisco Bay/Sacramento-San Joaquin Delta Estuary.* The plan was amended in 1991, 1995 and most recently in December 2006. This plan supplements the two regional Basin Plans that cover the estuary and establishes a comprehensive set of designated uses for all parts of the Bay and Delta. The plan describes the uses as existing uses.

The site-specific selenium criteria in this proposed rule are intended to protect aquatic life and aquatic-dependent wildlife, including federally listed threatened and endangered species, in the San Francisco Bay and Delta. The designated uses in the SWRCB water quality control plan for the protection of aquatic life and aquatic-dependent wildlife are listed in Table 1. The proposed criteria will establish levels of selenium that protect California's designated uses for the estuary.

TABLE 1—EXISTING DESIGNATED USES FOR THE SAN FRANCISCO BAY AND DELTA

Use	Abbreviation	Definition
Warm Freshwater Habitat	WARM	Uses of water that support warm water ecosystems including, but not limited to, preservation of aquatic habitats, vegetation, fish, or wildlife, including invertebrates.
Cold Freshwater Habitat	COLD	Uses of water that support cold water ecosystems including, but not limited to, preservation or enhancements of aquatic habitats, vegetation, fish, or wildlife, including invertebrates.
Migration of Aquatic Organisms	MIGR	Uses of water that support habitats necessary for the migration or other temporary activities by aquatic organisms, such as anadromous fish.
Spawning, Reproduction, and/or Early Development.	SPWN	Uses of water that support high quality aquatic habitats suitable for reproduction and early development of fish.
Estuarine Habitat	EST	Uses of water that support estuarine ecosystems including, but not limited to, preservation or enhancement of estuarine habitats, vegetation, fish, shellfish, or wildlife (*e.g.*, estuarine mammals, waterfowl, shorebirds).
Wildlife Habitat	WILD	Uses of water that support estuarine ecosystems including, but not limited to, preservation and enhancement of terrestrial habitats, vegetation, wildlife (*e.g.*, mammals, birds, reptiles, amphibians, invertebrates), or wildlife water and food sources.
Rare, Threatened, or Endangered Species.	RARE	Uses of water that support habitats necessary, at least in part, for the survival and successful maintenance of plant or animal species established under State or federal law as being rare, threatened, or endangered.

The proposed criteria are being set at levels that will protect aquatic life and aquatic-dependent wildlife consistent with WARM, COLD, EST, WILD and RARE uses, as well as protect aquatic life consistent with MIGR and SPWN uses.

E. Applicability of EPA Promgulated Water Quality Standards When Final

Under the CWA, Congress gave states primary responsibility for developing and adopting WQS for their waters (CWA section 303(a)–(c)). Although EPA is proposing selenium criteria for the protection of aquatic life and aquatic-dependent wildlife for marine and estuarine waters in California's San Francisco Bay and Delta, California continues to have the option to adopt and submit to EPA protective selenium criteria for these waters consistent with CWA section 303(c) and EPA's implementing regulations at 40 CFR part 131. EPA encourages California to expeditiously adopt protective criteria. Consistent with CWA section 303(c)(4), if California adopts and submits selenium criteria for the protection of aquatic life and aquatic-dependent wildlife, and EPA approves such criteria before finalizing this proposed rule, EPA would not proceed with the promulgation for those waters for which EPA approves California's criteria.

If EPA finalizes this proposed rule and California subsequently adopts and submits selenium criteria for the protection of aquatic and aquatic-dependent wildlife for marine and estuarine waters in the estuary, EPA proposes that once EPA approves California's WQS, the EPA-approved criteria in California's WQS would become the applicable criteria for CWA purposes and EPA's promulgated criteria would no longer be applicable criteria. EPA would undertake a rulemaking to withdraw the federal criteria for selenium, but that process would not delay California's approved criteria from becoming the sole applicable criteria for CWA purposes. EPA solicits comment on this approach.

F. Selenium Chemistry and Biology

Selenium is an element that occurs naturally in sediments of marine origin and enters the aquatic environment when rainwater comes into contact with deposits. Selenium can be further mobilized through anthropogenic activities such as agriculture irrigation, mining and petroleum refining. Once inorganic selenium is converted into a bioavailable form, it enters the food chain and can bioaccumulate. Depending on environmental conditions, one or another form of selenium such as selenate, selenite and organo-selenium, which differ in transformation rates and bioavailability, may predominate in the aquatic environment.

Selenium is an essential micro-nutrient, but the range between essential and toxic levels is narrow. A long-standing hypothesis is that toxicity occurs through biochemical pathways where excess selenium substitutes for sulphur in proteins, which alters their structure and function. More recent studies indicate that selenium may affect organisms through oxidative stress (see *Final Aquatic Life Ambient Water Quality Criteria for Selenium—Freshwater 2016,* U.S. EPA, Office of Water, EPA 822–R–16–006, June, 2016). Elevated selenium levels in fish and other wildlife inhibit normal growth and reduce reproductive success through effects that lower embryo survival, most notably teratogenesis.

Scientific studies indicate that selenium toxicity to aquatic life and aquatic-dependent wildlife is driven by diet (*i.e.*, the consumption of selenium-contaminated prey food) rather than by direct exposure in the water column. Selenium can accumulate in the aquatic food web through various routes and at various rates. At the bottom of the food chain, bacteria and algae can bioaccumulate selenium to levels that greatly exceed water column concentrations, and some invertebrates such as filter-feeding clams, can efficiently accumulate selenium from suspended organic and inorganic particles. In the San Francisco Bay and Delta, clam-based food webs accumulate selenium at a much higher rate than insect-based food webs, and the invasive clam species, *Potamocorbula amurensis,* now found throughout the estuary, can accumulate selenium at a much higher rate than supplanted clam species. Therefore, species that feed on this clam in the estuary, such as diving birds and sturgeon, are exposed to higher levels of bioaccumulated selenium than species that feed mainly on insects or higher-order species within an insect-based food chain. The vulnerability of a species to selenium toxicity is determined by a number of factors in addition to the amount of contaminated prey food consumed. A species' sensitivity to selenium, its population status, and the duration, timing and life stage of exposure are all factors to consider. In addition, the hydrologic conditions and water chemistry of a water body affect bioaccumulation; in general, slow-moving, calm waters or lentic waters enhance the production of bioavailable forms of selenium (selenite), while faster-moving waters or lotic waters limit selenium uptake given the rapid movement and predominant form of selenium (selenate). EPA considered these and other factors in determining the proposed selenium criteria for the estuary.

III. Rationale and Approach

A. Necessity

Ecological Health of the Estuary: The San Francisco Bay and Delta is the largest estuary on the West Coast of North America and, as part of the Pacific Flyway, serves as an important migratory stopover and wintering area for a variety of waterfowl. The estuary is formed by the intersection of two large river systems, the Sacramento and San Joaquin Rivers, which drain approximately 40 percent of California. The estuary is comprised of a series of large and small bays, marshes, and channels leading to the Pacific Ocean through the Golden Gate. The system is critical to California's ecological and economic well-being, and has long been the subject of competing interests. The estuary is the hub of California's water distribution system, providing drinking water to 25 million people, supplying irrigation for 4 million acres of farmland, and supporting over 750 different species of plants and animals. The estuary contributes to the area's economically important recreational and commercial fishing and boating industries. However, as a result of these competing demands and associated stresses, the ecosystem has suffered greatly and water quality in the estuary is impaired, habitat is shrinking, important fish populations are at an all-time low, and several species are listed as threatened or endangered. In recent years, pelagic (open water) species have declined, with some fish populations in serious, critical condition. This sudden collapse in pelagic species, referred to as the pelagic organism decline (or POD), has been intensively studied, but no one factor has been identified as the cause. Many factors are thought to be responsible for the decline of the estuary's health including water pollution, invasive species, water diversion and water project operations, ocean conditions (limited food and adverse temperatures), and habitat destruction and degradation. For a more detailed discussion, see *Unabridged Advanced Notice of Proposed Rulemaking for Water Quality Challenges in the San Francisco Bay/Sacramento-San Joaquin Delta Estuary,* U.S. EPA, February 2011; 76 FR 9709, February 22, 2011.

Plan for Restoration: In 2009, the Federal Bay Delta Leadership Committee, a Cabinet-level, multi-agency committee charged with coordinating federal responses to Bay and Delta issues, issued its Interim Federal Action Plan, which outlined the federal government's proposal to address water resource management issues in the estuary. The Interim Federal Action Plan included an action for EPA to "address the effectiveness of current regulatory mechanisms designed to protect water quality in the Delta and its tributaries, including standards for toxics, nutrients, and estuarine habitat protection." In response, after extensive public comment, EPA published *Water Quality Challenges in the San Francisco Bay/Sacramento-San Joaquin Delta Estuary: EPA's Action Plan* (the Action Plan) in August 2012. In the Action Plan, EPA concluded that existing programs under the CWA were not adequately safeguarding resources, and recommended seven priority activities to advance the protection and restoration of aquatic resources and ensure a reliable water supply in the watershed. The priority activities are: 1. Strengthen estuarine habitat protection standards; 2. Advance regional water quality monitoring and assessment; 3. Accelerate water quality restoration through Total Maximum Daily Loads (TMDLs); 4. Strengthen selenium water quality criteria; 5. Prevent pesticide pollution; 6. Restore aquatic habitats while managing methylmercury; and 7. Support the Bay Delta Conservation Plan (now called the California WaterFix). This proposed rule is intended to advance priority activity number four, Strengthen selenium water quality criteria.

Sources of Selenium: Sources of selenium in the estuary include the tributaries flowing into the Delta and Bay, municipal and industrial wastewater discharges, stormwater discharges, atmospheric deposition, and in-bay sediments. The largest contributors are the Sacramento and San Joaquin Rivers and the five oil refineries located along the Bay.

The headwaters of both rivers originate from snowmelt in the Sierra Nevada. The Sacramento River flows north to south into the Delta, and drains the northern portion of the Central Valley. The San Joaquin River flows east to west, then turns and flows south to north into the Delta, and drains the southern and central portions of the Central Valley, which are used extensively for farming. The two rivers meet in the Delta near Antioch and flow west into the northern reaches of the Bay, then southwest to the Pacific Ocean.

Selenium concentrations in the San Joaquin River are elevated from selenium enriched soils on the west side of the Central Valley. Agricultural irrigation practices mobilize naturally occurring selenium in the heavy soils derived from marine shale and sediment. Selenium concentrations in the Sacramento River are much lower than in the San Joaquin River and are generally at natural background levels.[7] Flow volumes from each river vary depending on the water year type and season, and for the San Joaquin River, the volume of diversions. Therefore, selenium loads from the rivers vary, while loads from the refineries are more constant.

The San Joaquin watershed is much drier than the Sacramento watershed, and flows to the Bay from the San Joaquin River are significantly smaller than those from the Sacramento River. In addition, dams for hydropower and flood control further limit flows from the San Joaquin. Flow volume from the

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[7] *Water Quality Survey for Selenium in the Sacramento River and its Major Tributaries,* California Regional Water Quality Control Board, Central Valley Region, 1988, Sacramento, California.

San Joaquin into the Delta as measured at Vernalis between 2002 and 2011 has ranged from approximately 8 to 30 percent of the flow volume from the Sacramento River at Freeport during the same time period.[8] At Clifton Court Forebay in the San Joaquin Delta below Vernalis, the State Water Project pumps water from the Delta to the California Aqueduct for delivery to Southern California, and the Central Valley Project pumps water to the Delta Mendota Canal for delivery to Central Valley farmers. As a result of these diversions, even less flow from the San Joaquin enters the northern part of the Bay.

Although flows from the San Joaquin are much smaller than flows from the Sacramento, selenium concentrations have been significantly higher than concentrations in the Sacramento. In 1998 and 1999, concentrations of dissolved selenium in the San Joaquin River averaged 0.71 µg/L, and ranged from 0.40 to 1.07 µg/L at Vernalis.[9] Concentrations in the San Joaquin have declined recently, but continue to be higher than levels in the Sacramento River. Recent data from 2010–2012 show that dissolved selenium concentrations range from 0.207 to 0.47 µg/L in the San Joaquin.[10] Concentrations in the Sacramento have not materially changed during this time period. In 1998 and 1999, concentrations of dissolved selenium averaged 0.07 µg/L, and ranged from 0.05 to 0.11 µg/L at Freeport.[9] More recent data from 2010–2012 show levels between 0.062 and 0.09 µg/L.[10]

Concentrations of dissolved selenium in the Delta and in the northern and central portions of the Bay from 1998–1999 ranged from 0.070 to 0.320 µg/L.[9] Recent data from 2010–2012 show that concentrations have decreased, and range from 0.058 to 0.13 µg/L.[10]

Agriculture: Selenium concentrations in the San Joaquin River and the estuary are decreasing, in part, as a result of conservation actions from the agricultural industry and California's implementation of three selenium TMDLs in the Central Valley. TMDLs for a portion of the San Joaquin River, the Grassland Marshes, and Salt Slough (a tributary) are being implemented through Waste Discharge Requirements (WDRs) (permits) and the Grassland Bypass Project to reduce and reroute discharges of agricultural return flows from the west side of the watershed around sensitive wetlands.

Between 1986 and 1996, before construction of the Grassland Bypass Project and implementation of the TMDLs, selenium loads in the San Joaquin at Patterson and Crows Landing below the confluence of the Merced River averaged 8,129 pounds per year (lbs/year). Since 2000, selenium loads have ranged from 1,526–6,353 lbs/year, with the lowest loads in recent years.[11] Between the mid-1990s and the mid-2000s, selenium loading to surface waters decreased by approximately one-half to two-thirds through agricultural water conservation measures such as harvesting crops that require less water, drip irrigation, water recycling and reuse on salt-tolerant crops, and land retirement. Although the final WDR loading targets have not been met, the agriculture industry has helped reduce selenium loads in the watershed. Final targets are scheduled to be achieved by 2019.

Refineries: Another source of selenium to the estuary is wastewater from the processing of selenium-rich crude oil, from the five major oil refineries located along the Bay. The recent decreases in selenium concentrations in the Bay are also the result of the refineries reducing selenium loads in wastewater discharges in response to California's implementation of more stringent NPDES permit limits. Selenium levels in crude vary, and the crude from the San Joaquin Basin can contain significantly higher levels than other sources of crude. Available data indicate that from 1986 through 1992, the cumulative selenium load to the Bay from the refineries averaged approximately 5,000 lbs/year, and ranged from 3,953 to 5,783 lbs/year.[9] In 1991, California required the refineries to reduce their mass discharge of selenium and achieve more stringent wastewater concentration limits. The refineries achieved their mass-based limits and revised concentration limits by 1998. The average cumulative selenium load for all refineries since 1999 has been approximately 1,200 lbs/year, down approximately 75% from early 1990 levels.[9] Activities undertaken by both the agriculture industry and the refineries have helped to reduce selenium loads to the Bay.

Invasive Clam Species: In the fall of 1986, after major flooding in the spring had wiped out large parts of the existing benthic community, a small bivalve was discovered in the northern reaches of San Francisco Bay.[12] Its population rapidly increased and spread throughout the estuary. The species, *Potamocorbula amurensis* (*P. amurensis*), commonly known as *Corbula,* is native to China, Japan, and Korea, and is thought to have been introduced to the estuary from ballast water. Adults tolerate a wide range of salinity (1 to 32 parts per thousand), and although *Corbula* flourish in subtidal waters, they can also live in intertidal mudflats.[12] The species is remarkably efficient in accumulating selenium from its environment[13] and is responsible for the accelerated bioaccumulation of selenium in the food chain of the fish and bird species in the Bay and Delta ecosystem. The species most at risk in the estuary from the *Corbula* invasion are believed to be clam-eating fish and bird species such as green and white sturgeon, scoter and scaup.

Need for Revised Criteria: EPA now has updated scientific information on selenium fate and bioaccumulation, as well as updated information on the Bay and Delta estuary ecosystem that was not available when EPA developed the existing Bay and Delta selenium criteria in the NTR. These data indicate the need for revised criteria. The explosion of the *Corbula* population in the early 1990s has drastically changed the food web and selenium bioaccumulation dynamics in the Bay and Delta. The Ecosystem-Scale Selenium Model for the San Francisco estuary allows EPA to develop revised selenium criteria that account for site-specific and species-specific characteristics, including species with greater exposure and/or susceptibility to selenium. In doing so, EPA is following the requirements at 40 CFR 131.11(a)(1) to derive criteria that are based on a sound scientific rationale and protect the most sensitive uses, which in the case of the Bay and Delta include migration of aquatic organisms (*e.g.,* anadromous fish species), and habitat for rare, threatened and endangered species.

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[8] USGS National Water Information System, Surface-Water Annual Statistics for California at: *http://waterdata.usgs.gov/ca/nwis/nwis* (search terms: Surface Water; Annual Flow Data (Stream); Sacramento County at Freeport, USGS 11447650, and San Joaquin County at Vernalis, USGS 11303500, 2002–2012, compare discharge in cubic feet per second based on daily-mean data for water years 2002–2011).

[9] *Ecosystem-Scale Selenium Modeling in Support of Fish and Wildlife Criteria Development for the San Francisco Bay-Delta Estuary, California,* Theresa S. Presser and Samuel N. Luoma, U.S. Geological Survey, 2010, Menlo, Park, California; and using data from: (1) *Selenium Biogeochemistry in the San Francisco Estuary: Changes in Water Column Behavior,* G.A. Cutter and L.S. Cutter, 2004, Estuarine, Coastal, and Shelf Science, 61:3 pp 463–476; (2) *Sources and Biogeochemical Cycling of Particulate Selenium in the San Francisco Bay Estuary,* M.A. Doblin, S.B. Baines, L.S. Cutter, and G.A. Cutter, 2006, Estuarine, Coastal, and Shelf Science, 76:4 pp. 681–694; and (3) *Transport, Transformation, and Effects of Selenium and Carbon in the Delta of the Sacramento-San Joaquin Rivers: Implications for Ecosystem Restoration,* L. Lucas and A.R. Stewart, 2007, CALFED Ecosystem Restoration Program, Agreement No. 4600001955, Project No. ERP–01–C07.

[10] *North San Francisco Bay Selenium Characterization Study, Final Report (Appendix B Data Tables),* Tetra Tech, Inc. on behalf of Western States Petroleum Association, 2012, Lafayette, California.

[11] *Grassland Bypass Project Annual Report 2010–2011,* San Francisco Estuary Institute for the Grassland Bypass Project Oversight Committee, 2013, Chapter 1 (Table 7) by Michael C.S. Eacock and Stacy Brown, U.S. Bureau of Reclamation, Fresno, California.

[12] *The Exotics Guide: Non-native Marine Species of the North American Pacific Coast,* 2011, Andrew N. Cohen, Center for Research on Aquatic Bioinvasions, Richmond, California, and San Francisco Estuary Institute, Oakland, California. *http://www.exoticsguide.org.*

[13] *Food Web Pathway Determines How Selenium Affects Ecosystems: A San Francisco Bay Case Study,* 2004, A. Robin Stewart, Samuel N. Luoma, Christian E. Schlekat, and Kathryn A. Hieb, Environmental Science and Technology, 38:4519–4526.

Although conditions have improved from reduced agriculture and refinery loads, ambient levels of selenium are not consistently below harmful levels in all parts of the estuary. Revised criteria are necessary to help ensure that protective levels are attained in all parts of the water body and are maintained in the future to protect designated uses. Several indigenous species are listed under the ESA as threatened or endangered, including green sturgeon, Chinook salmon, steelhead trout, delta smelt and the California Ridgway's rail, and many migratory bird species use the estuary as a wintering ground, including greater and lesser scaup, and white-winged, surf, and black scoter. The analyses to develop the fish tissue and the avian egg tissue benchmarks used in the modeling, and the modeling results used to derive the proposed water column criteria, indicate the health of these species would be negatively impacted from exposure to selenium water column concentrations above 0.2 µg/L, which would be allowed to occur under the existing NTR selenium criterion of 5.0 µg/L. Accordingly, EPA finds that it is necessary to propose revised and more protective criteria for selenium in order to help ensure the continued protection of these vulnerable species and associated designated uses.

B. Administrator's Determination of Necessity

Because California's existing aquatic life criteria for selenium in the salt and estuarine waters of the San Francisco Bay, upstream to and including Suisun Bay and the Sacramento-San Joaquin Delta, as promulgated by EPA in the NTR, are not protective of the applicable designated uses per the CWA and EPA's regulations at 40 CFR 131.11, EPA determines under CWA section 303(c)(4)(B) that new or revised WQS for the protection of aquatic life and aquatic-dependent wildlife are necessary to meet the requirements of the CWA for these California waters. EPA, therefore, proposes the revised selenium aquatic life and aquatic-dependent wildlife criteria in this rule in accordance with this 303(c)(4)(B) determination. EPA's determination is not itself a final action, nor part of a final action, at this time. After consideration of comments on the proposed rule, EPA will take final agency action on this rulemaking. It is at that time that any change to the water quality standards applicable in California would occur.

C. Approach

USGS Ecosystem-Scale Selenium Model: The Ecosystem-Scale Selenium Model uses species-specific and hydrologic site-specific information to model the fate and biological uptake of selenium in an aquatic ecosystem through diet. The model was originally developed for the San Francisco estuary. It conceptualizes and quantifies several key variables in order to predict how selenium moves from the water environment to wildlife species through the food chain. It can link selenium tissue concentrations in fish or avian wildlife to dissolved and particulate selenium concentrations in the water environment and to selenium tissue concentrations in prey food.

Starting in 2003, USGS worked with the Services and EPA to model the San Francisco Bay and Delta using various scenarios and endpoints (see the USGS Report). Using the best available data for the estuary, USGS modeled a clam-based food web from the Golden Gate through Suisun Bay to Chipps Island and an insect-based food web from Benicia to Rio Vista (in the Sacramento River Delta area) and to Stockton (in the San Joaquin River Delta area). Using site-specific partitioning coefficients to determine rates of selenium transformation between dissolved and particulate phases, the model can predict how efficiently selenium enters the base of the food web. Once selenium enters the food web, using site-specific trophic transfer factors, which relate selenium concentrations in a species to selenium concentrations in its food, the model can predict how efficiently selenium moves up into prey food and to a predator species. Alternatively, a protective tissue level of selenium in an upper trophic level fish species or in a terrestrial wildlife species (any predator species) can be used to back-calculate and predict the protective concentration of selenium in the species' prey, and the protective concentration of dissolved and particulate selenium at the base of its food web in the aquatic environment.

EPA Modeling: Using information from the Services on important and/or vulnerable fish and avian wildlife species in the estuary, and building on the USGS modeling of the estuary, EPA modeled the estuary to develop site-specific scenarios on which to base the proposed criteria (see *Technical Support Document for the Proposed Aquatic Life and Aquatic-Dependent Wildlife Selenium Water Quality Criteria for the San Francisco Bay and Delta (2016),* US EPA Region 9, June, 2016).

EPA considered various protective (benchmark) tissue values for representative fish and avian wildlife species to use in the modeling. EPA found that the most appropriate tissue benchmark values for fish species in the estuary are the recommended values in EPA's recent national recommended freshwater aquatic life criterion for selenium[14] and for avian species in the estuary, the egg tissue value discussed in EPA's approval of the State of Utah's avian wildlife criterion for Gilbert Bay of the Great Salt Lake.[15] These benchmark values represent a 10% Effect Concentration (EC10), which is a concentration or level of a pollutant that may adversely affect up to 10% of a species population. In the national recommended freshwater aquatic life criterion for selenium, EPA used EC10 concentrations to develop the selenium water quality criterion values.[14]

EPA modeled two food webs in the estuary, a clam-based web and an insect-based web, to determine protective dissolved, particulate and prey-tissue selenium values. EPA modeled a clam-based food chain for fish and two clam-based food chains for birds that consume *Corbula* from the estuary, each chain representing at-risk fish and bird species in the estuary. The clam-based fish modeling represented white and juvenile green sturgeon, important species in the estuary that EPA determined are the most vulnerable clam-eating fish species. Although white sturgeon are not listed under the ESA, green sturgeon are threatened and the estuary is designated as critical habitat for the species. Since other important vulnerable fish species in the estuary such as Sacramento splittail consume less *Corbula* than sturgeon, the other species should be protected if sturgeon are protected.

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[14] *Final Aquatic Life Ambient Water Quality Criterion for Selenium—Freshwater 2016,* EPA 822–R–16–006, US EPA, Office of Water, 2016, Washington, DC.

[15] *EPA Action on the Gilbert Bay Selenium Criterion and Footnote (14), and Enclosure,* US EPA Region 8, 2011, Denver, Colorado.

EPA modeled two clam-based food web scenarios for at-risk avian wildlife to represent two different patterns of avian clam-consumption in the estuary. The California Ridgway's rail (formerly the California clapper rail) is a small, endangered, indigenous bird that lives year-round in the estuary and eats mostly mollusks, but only a small percentage of *Corbula*. The five species of migratory diving waterfowl, greater and lesser scaup and white-winged, surf, and black scoter, live part-time in the estuary, but up to 90% of their diet may consist of *Corbula* from the estuary. These differences in living and eating patterns are sufficiently significant that EPA ran the model for each separately to ensure the criteria are protective of all avian wildlife in the Bay and Delta estuary.

Lastly, EPA modeled insect-eating fish to represent two important anadromous species, the endangered Chinook salmon and the threatened steelhead trout, and an important, threatened, indigenous species in the estuary, the delta smelt. Since anadromous species use the estuary as a migratory corridor, and adults returning to spawn do not feed during in-migration, EPA considered the diet of juveniles as they out-migrate through the estuary to the Pacific Ocean. Delta smelt, and juvenile Chinook salmon and steelhead trout, consume mainly insects, and do not feed on *Corbula*.

The model results indicate that clam-eating fish and clam-eating bird species are the most vulnerable species, and require lower dissolved and particulate water column selenium concentrations in the estuary than insect-eating fish in order to ensure that tissue levels stay below concentrations that may cause adverse effects. EPA considered the dissolved water column, particulate water column, and prey-tissue values necessary to protect all three categories of species in setting the proposed regulatory criteria values.

D. Proposed Criteria

Water quality criteria establish the maximum allowable pollutant level that is protective of the designated uses of a water body. States (or in this case, EPA) adopt criteria as part of water quality standards. Under the CWA, water quality standards are used to derive effluent limitations in permits for point source dischargers, thereby limiting the amount of pollutants that may be discharged into a water body to maintain its designated uses. EPA is proposing selenium water quality criteria for the San Francisco Bay and Delta in tissue and in the water column (both dissolved and particulate selenium concentrations). EPA is proposing selenium tissue concentration criteria because they reflect biological uptake through diet, the predominant pathway for selenium toxicity, and because they are most predictive of the observed biological endpoint of concern: reproductive toxicity. However, tissue concentrations present challenges when attempting to use them to regulate or limit sources of pollutants. In order to facilitate monitoring and regulation of pollutant discharges, EPA is also proposing dissolved and particulate water column selenium concentration criteria needed to ensure the tissue concentration criteria are met. Because EPA used site-specific species and hydrologic information in the Ecosystem-Scale Selenium Model to determine the protective dissolved and particulate water column and prey selenium concentrations associated with the predator tissue concentrations, EPA proposes that the criteria in different media are equivalently protective and exceedance of any one medium would indicate an impairment of the designated use.

The proposed tissue criteria consist of fish tissue criteria, a whole body criterion of 8.5 micrograms per gram (μg/g) dry weight (dw) or a muscle criterion of 11.3 μg/g dw, and a clam (or prey) tissue criterion of 15 μg/g dw. EPA is proposing each of these tissue criteria as an instantaneous measurement not to be exceeded. The proposed chronic water column criterion is a dissolved selenium criterion of 0.2 μg/L, and the proposed particulate criterion is 1 μg/g. Each of these two values is a 30-day average, not to be exceeded more than once in three years.

Although selenium may cause acute toxicity at high concentrations, *i.e.*, toxicity from a brief but highly elevated concentration of selenium in the water, chronic dietary exposure poses the highest risk to aquatic life and aquatic-dependent wildlife. Chronic toxicity occurs primarily through maternal transfer of selenium to eggs and causes subsequent reproductive effects. These chronic effects are observed at much lower concentrations than acute effects. Aquatic and aquatic-dependent communities are expected to be protected by the chronic criteria from any potential acute effects of selenium and an acute toxicity criterion is not pertinent for regulatory purposes. However, some high, short-term exposures could be detrimental by causing significant long-term, residual, bioaccumulative effects, *i.e.*, by the introduction of a selenium load into the system. Therefore, EPA is also proposing an intermittent exposure water quality criterion to prevent long-term detrimental effects from these high, short-term exposures. EPA derived the proposed intermittent criterion as a fraction of the 30-day load based on the chronic water column criterion, after accounting for the background selenium concentration. EPA expects that a short-term, significantly elevated selenium scenario would rarely occur in the San Francisco Bay and Delta due to the large volume of water and tidal influences within the estuary that dilute and flush selenium loads through the Golden Gate. EPA is proposing this intermittent criterion to ensure protection of the ecosystem and for consistency with EPA's national recommended aquatic life criterion for selenium. A summary of the proposed criteria is included in Table 2.

Table 2. Proposed Selenium Water Quality Criteria for the San Francisco Bay and Delta

Media Type	Tissue		Water Column[1]		
			Dissolved		Particulate
Criteria	**Fish Whole Body or Muscle**	**Clam**	**Chronic**	**Intermittent Exposure[2]**	**Chronic**
Magnitude	8.5µg/g dw whole body or 11.3 µg/g dw muscle	15 µg/g dw	0.2 µg/L	$WQC_{int} = \frac{0.2\ \mu g/L - C_{bkgrnd}(1 - f_{int})}{f_{int}}$	1 µg/g dw
Duration	Instantaneous measurement	Instantaneous measurement	30 days	Number of days/month with an elevated concentration	30 days
Frequency	Not to be exceeded	Not to be exceeded	Not more than once in three years	Not more than once in three years	Not more than once in three years

[1] Dissolved and particulate water column values are based on total selenium (includes all oxidation states, i.e., selenite, selenate, organic selenium and any other forms) in water.

[2] Where C_{bkgrnd} is the average background selenium concentration in µg/L, and f_{int} is the fraction of any 30-day period during which elevated selenium concentrations occur, with f_{int} assigned a value ≥ 0.033 (corresponding to one day).

The proposed criteria apply to all waters of the San Francisco Bay and Delta with salinities of greater than 1 part per thousand (ppt) 95% or more of the time.

IV. Implementation and Alternative Regulatory Approaches

California will have considerable discretion to implement these selenium criteria, once finalized, through various water quality control programs, including the NPDES program, which limits discharges to waters except in compliance with an NPDES permit. Among other things, EPA's regulations: (1) Specify how states and authorized tribes establish, modify or remove designated uses, (2) specify the requirements for establishing criteria to protect designated uses, including criteria modified to reflect site-specific conditions, (3) authorize states and authorized tribes to adopt WQS variances to provide time to achieve the applicable WQS, and (4) allow states and authorized tribes to include compliance schedules in NPDES permits to provide time for dischargers to achieve effluent limits based on the applicable WQS. Designated uses, site-specific criteria, variances, and compliance schedules are discussed in more detail below.

Designated Uses: EPA's proposed selenium criteria apply to marine and estuarine waters in the San Francisco Bay and Delta where the protection of aquatic life and aquatic-dependent wildlife are designated uses (see *The Water Quality Control Plan for the San Francisco Bay/Sacramento-San Joaquin Delta Estuary,* SWRCB, December 13, 2006). The federal regulations at 40 CFR 131.10 provide information on establishing, modifying, and removing designated uses. If California removes designated uses such that no aquatic life or aquatic-dependent wildlife uses apply to any particular water body segment affected by this rule and adopts the highest attainable use,[16] and EPA finds that removal to be consistent with CWA section 303(c) and the implementing regulations at 40 CFR part 131, then the federal selenium aquatic life and aquatic-dependent wildlife criteria would no longer apply to that water body segment. Instead, any criteria associated with the newly designated highest attainable use would apply to that water body segment.

Site-Specific Criteria: The regulations at 40 CFR 131.11 specify requirements for modifying water quality criteria to reflect site-specific conditions. In the context of this rulemaking, a site-specific criterion (SSC) is an alternative value to the federal selenium criteria that would be applied on an area-wide or water body-specific basis that meets the regulatory test of protecting the designated uses, being scientifically defensible, and ensuring the protection and maintenance of downstream WQS. A SSC may be more or less stringent than the otherwise applicable federal criteria. A SSC may be appropriate when further scientific data and analyses can bring added precision to express the concentration of selenium that protects the aquatic life- and aquatic-dependent wildlife-related designated uses in a particular water body or portion of a water body. Since the San Francisco Bay and Delta is a large water body, a different SSC may be appropriate for a small segment of the estuary, *e.g.*, South San Francisco Bay, if differing flow dynamics indicate that different criteria may be more appropriate. As discussed in section II. E., EPA proposes that once EPA approves criteria that California adopts and submits after EPA finalizes this proposed rule, the site-specific EPA-approved criteria in California's WQS would become effective for CWA purposes and EPA's promulgated criteria would no longer apply.

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[16] Highest attainable use is the modified aquatic life, wildlife, or recreation use that is both closest to the uses specified in section 101(a)(2) of the CWA and attainable, based on the evaluation of the factor(s) in 40 CFR 131.10(g) that preclude(s) attainment of the use and any other information or analyses that were used to evaluate attainability. There is no required highest attainable use where the state demonstrates the relevant use specified in section 101(a)(2) of the CWA and sub-categories of such a use are not attainable (see 40 CFR 131.3(m)).

Variances: EPA's regulations at 40 CFR part 131.14 authorize states and authorized tribes to adopt WQS variances to provide time to achieve the applicable WQS. 40 CFR part 131 defines WQS variances at 131.3(o) as time-limited designated uses and supporting criteria for a specific pollutant(s) or water quality parameters(s) that reflect the highest attainable conditions during the term of the WQS variance. WQS variances adopted in accordance with 40 CFR part 131 allow states and authorized tribes to address water quality challenges in a transparent and predictable way. Variances help states and authorized tribes focus on making incremental progress in improving water quality, rather than pursuing a downgrade of the underlying water quality goals through a designated use change, when the current designated use is difficult to attain. EPA is proposing criteria that apply to use designations that California has already established. California currently has authority to use variances when implementing the criteria, as long as such variances are adopted consistent with 40 CFR 131.14 (see *Policy for Implementation of Toxics Standards for Inland Surface Waters, Enclosed Bays, and Estuaries of California,* Section 5.3, SWRCB, March 2, 2000, amended February 24, 2005; and *Procedures for Case-by-Case Exceptions from Criteria/ Objectives,* SWRCB, April 15, 2008). California may use EPA-approved variance procedures, with respect to a temporary modification of its uses as it pertains to any federal criteria, when adopting such variances.

Compliance Schedules: EPA's regulations at 40 CFR 122.47 and 40 CFR 131.15 allow states and authorized tribes to include permit compliance schedules in their NPDES permits, when appropriate, in order to accommodate a discharger's need for additional time to meet its water quality-based effluent limits (WQBELs) implementing applicable WQS (such as time needed for facility upgrades and operational changes).

In 1990, EPA concluded that before a permitting authority can include a compliance schedule for a WQBEL in an NPDES permit, the state or authorized tribe must authorize its use in its WQS or implementing regulations.[17] A permit compliance schedule authorizing provision (CSAP) authorizes, but does not require, the permit issuing authority to include compliance schedules in permits. EPA's approval of the state's or authorized tribe's permit CSAP as a WQS pursuant to 40 CFR 131.15 ensures that any NPDES permit that contains a compliance schedule meets the requirement that the WQBEL and any compliance deadlines derive from and comply with applicable WQS.

California is authorized to administer the NPDES program in the state, and has adopted several mechanisms to authorize compliance schedules in NPDES permits. In 2008, California adopted a statewide CSAP that EPA subsequently approved under CWA section 303(c), the *Policy for Compliance Schedules in National Pollutant Discharge Elimination System Permits,* SWRCB Resolution No. 2008–0025, April 15, 2008. This EPA-approved regulation authorizes the use of permit compliance schedules consistent with 40 CFR 131.15, and is not affected by this rule. The CSAP will allow California to grant compliance schedules, as appropriate, based on the federal selenium criteria for the Bay and Delta, once these criteria are finalized (see letters dated May 20, 2016 and May 27, 2016 from the SWRCB to EPA in the docket for this rule).

V. Endangered Species Act

Pursuant to section 7(a) of the ESA, EPA is consulting with the FWS and NMFS concerning EPA's rulemaking action for selenium water quality criteria in the San Francisco Bay and Delta. EPA will initiate informal consultation, and will transmit to the Services documentation that supports the selenium water quality criteria in this proposed rule. As a result of this consultation, EPA may modify some provisions of this proposed rule. The basis for the selenium criteria in this proposed rule stems from many years of ongoing collaboration between EPA and the Services. EPA, FWS and NMFS will continue to work closely together on this ESA consultation process.

VI. Economic Analysis

POTWs and industrial point sources that discharge to the Bay and Delta may incur some incremental compliance actions and costs as a result of the proposed criteria. California has NPDES permitting authority for these dischargers, and retains considerable discretion in implementing standards. EPA evaluated the potential costs to the municipal and industrial NPDES dischargers associated with state implementation of EPA's proposed dissolved water column criterion. EPA did not evaluate the potential costs associated with state implementation of EPA's proposed particulate water column criterion because particulate data are not available and because the state has discretion concerning implementation. This analysis is documented in *Economic Analysis for Proposed Aquatic Life and Aquatic-Dependent Wildlife Criteria for Selenium in the San Francisco Bay and Delta, California* (prepared for EPA by Abt Associates in Partnership with PG Environmental, LLC, June, 2016), which can be found in the docket for this rulemaking.

NPDES-permitted facilities that discharge selenium to affected portions of the Bay and Delta could potentially incur compliance costs. The types of affected facilities could include industrial facilities and POTWs discharging wastewater to surface waters (*i.e.,* point sources). EPA expects that dischargers will use the same types of controls as they are currently using to comply with existing selenium criteria applicable to the Bay and Delta, to come into compliance with the revised criteria. Since the state recently adopted the North San Francisco Bay Selenium TMDL, and the TMDL requirements and underlying analyses indicate that current ambient water quality conditions (dissolved selenium levels at or below 0.2 μg/L) will be maintained, EPA did not include costs associated with point sources covered in the TMDL analysis.

EPA did not identify incremental compliance costs for nonpoint sources. Unlike point sources, California typically does not require nonpoint sources to achieve numeric WQBELs; instead, these sources often have best management practice (BMP) requirements, as well as load allocations associated with TMDLs. Regional Boards have already established TMDLs for selenium in the Lower San Joaquin River and the North San Francisco Bay, and EPA assumes the proposed selenium criteria will not result in the need for additional controls by nonpoint sources in those areas. It is uncertain to what extent nonpoint sources contribute selenium loadings to the Lower and South San Francisco Bay. EPA assumes that naturally-occurring selenium may be the primary source of selenium in the Lower and South San Francisco Bay, and as such, the incremental controls and costs for nonpoint sources as a result of the proposed criteria will not be significant.

A. Identifying Affected Entities

Potentially affected facilities include those discharging to waters subject to the proposed criteria (*i.e.,* marine or estuarine waters) that are not already included in the North San Francisco

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[17] *In the Matter of Star-Kist Caribe, Inc.* 3 EAD 172 (April 16, 1990).

Bay Selenium TMDL. EPA identified 16 such point source facilities, all discharging to the Lower and South San Francisco Bay. Of these potentially affected facilities, 14 are POTWs and 2 are industrial dischargers (the San Francisco International Airport and the Bottling Group, LLC). Table 3 summarizes these potentially affected facilities by type and category.

TABLE 3—POTENTIALLY AFFECTED FACILITIES

Category	Minor	Major	All
Municipal	1	13	14
Industrial	1	1	2
Total	2	14	16

B. Method for Estimating Costs

For all potentially affected facilities, EPA used the last five years of effluent data (when available) and ambient monitoring data from the relevant monitoring station to determine whether there is reasonable potential for the facility to cause or contribute to an excursion above the proposed dissolved water column criterion for selenium. For those facilities that have reasonable potential, EPA calculated projected effluent limits. EPA conducted reasonable potential analyses and calculated effluent limitations for each facility based on California's permitting practices.[18] In instances where the facility's maximum effluent selenium concentration exceeded the projected effluent limitations under the proposed criterion, EPA determined the likely compliance scenarios and costs. Following California's *Policy for Implementation of Toxics Standards for Inland Surface Waters, Enclosed Bays, and Estuaries of California* may result in a conservative evaluation for some point sources. However, the Regional Boards have substantial discretion to apply other implementing permitting procedures that are consistent with the Policy's requirements, and may elect to follow different methods to determine whether effluent limits are necessary and/or the value of the effluent limitations. These alternative methods may result in fewer facilities requiring action and/or less stringent permit limitations.

EPA assumed that dischargers would pursue the least cost means of compliance with WQBELs. Incremental compliance actions attributable to the proposed rule may include process optimization, source controls, end-of-pipe treatment, and alternative compliance mechanisms (*e.g.*, site-specific criteria, variances, and dilution credits). For plants discharging at levels above California's minimum quantitation level, EPA has assumed that the facility will pursue conventional treatment methods to comply with the projected effluent limitations. Facilities operating below the quantitation level are discharging near the projected limitations, and EPA has assumed that compliance is likely to be achievable using process optimization methods. EPA annualized capital costs over 20 years using a 3% discount rate to obtain total annual costs per facility.

C. Results

Of the 16 potentially affected facilities that EPA identified, 14 were found to have reasonable potential to cause or contribute to an excursion above the proposed criterion. For compliance with revised WQBELs under the proposed rule, EPA estimates the total annual cost to be approximately $16 million across the 14 facilities. Of these costs, nearly all are attributable to POTW dischargers (*i.e.*, 13 POTWs and one industrial facility, the San Francisco International Airport).

VII. Statutory and Executive Orders

A. Executive Order 12866 (Regulatory Planning and Review) and Executive Order 13563 (Improving Regulation and Regulatory Review)

This action is not a significant regulatory action and was, therefore, not submitted to the Office of Management and Budget (OMB) for review. The proposed rule does not establish any requirements directly applicable to regulated entities or other sources of toxic pollutants. However, these WQS may serve as a basis for development of NPDES permit limits. California has NPDES permitting authority, and retains considerable discretion in implementing WQS. In the spirit of Executive Order 12866, EPA evaluated the potential costs to NPDES dischargers associated with state implementation of EPA's proposed criteria. This analysis, *Economic Analysis for Proposed Aquatic Life and Aquatic-Dependent Wildlife Criteria for Selenium in the San Francisco Bay and Delta, California,* is summarized in section VI. of the preamble and is available in the docket.

B. Paperwork Reduction Act (PRA)

This action does not impose an information collection burden under the PRA. While actions to implement these WQS could entail additional paperwork burden, this action does not directly contain any information collection, reporting, or record-keeping requirements.

C. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. This action will not impose any requirements on small entities. Small entities, such as small businesses or small governmental jurisdictions, are not directly regulated by this rule.

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. As these water quality criteria are not self-implementing, the action imposes no enforceable duty on any state, local or tribal governments or the private sector.

E. Executive Order 13132 (Federalism)

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government. This rule does not alter California's considerable discretion in implementing these WQS, nor would it preclude California from adopting WQS that meet the requirements of the CWA, either before or after promulgation of the final rule, which would eliminate the need for federal standards upon EPA approval of the state WQS. Thus, Executive Order 13132 does not apply to this action.

In the spirit of Executive Order 13132 and consistent with EPA policy to promote communications between EPA and state and local governments, EPA specifically solicits comments on this proposed action from state and local officials.

F. Executive Order 13175 (Consultation and Coordination With Indian Tribal Governments)

This action does not have tribal implications as specified in Executive Order 13175. This proposed rule does not impose substantial direct compliance costs on federally recognized tribal governments, nor does it substantially affect the relationship between the federal government and tribes, or the distribution of power and responsibilities between the federal government and tribes. Thus, Executive Order 13175 does not apply to this action.

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[18] Pursuant to the *Policy for Implementation of Toxics Standards for Inland Surface Waters, Enclosed Bays, and Estuaries of California,* SWRCB, California Environmental Protection Agency, March 2, 2000, amended February 24, 2005.

Consistent with the EPA Policy on Consultation and Coordination with Indian Tribes, EPA consulted with tribal officials during the development of this action. EPA will continue to communicate with the tribes prior to its final action.

G. Executive Order 13045 (Protection of Children From Environmental Health and Safety Risks)

The EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of "covered regulatory action" in section 2–202 of the Executive Order. This action is not subject to Executive Order 13045 because it does not concern an environmental health risk or safety risk.

H. Executive Order 13211 (Actions That Significantly Affect Energy Supply, Distribution, or Use)

This action is not subject to Executive Order 13211, because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act of 1995

This proposed rulemaking does not involve technical standards.

J. Executive Order 12898 (Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations)

The human health or environmental risk addressed by this action will not have potential disproportionately high and adverse human health or environmental effects on minority, low-income or indigenous populations. The criteria in this proposed rule will support the health and abundance of aquatic life and aquatic-dependent wildlife in the San Francisco Bay and Delta and will, therefore, benefit all communities that rely on these ecosystems.

List of Subjects in 40 CFR Part 131

Environmental protection, Indians-lands, Intergovernmental relations, Reporting and recordkeeping requirements, Water pollution control.

Dated: June 30, 2016.

Gina McCarthy,

Administrator.

For the reasons set forth in the preamble, EPA proposes to amend 40 CFR part 131 as follows:

PART 131—WATER QUALITY STANDARDS

■ 1. The authority citation for part 131 continues to read as follows:

Authority: 33 U.S.C. 1251 *et seq.*

Subpart D—Federally Promulgated Water Quality Standards

■ 2. Section 131.36 is amended by revising paragraph (d)(10)(ii) table entry for "Waters of San Francisco Bay upstream to and including Suisun Bay and the Sacramento-San Joaquin Delta" to read as follows:

§ 131.36 Toxics criteria for those states not complying with Clean Water Act section 303(c)(2)(B).

* * * * *

(d) * * *

(10) * * *

(ii) * * *

Water and use classification	Applicable criteria
* * * * * * *	
Waters of San Francisco Bay upstream to and including Suisun Bay and the Sacramento-San Joaquin Delta.	These waters are assigned the criteria in: Column B1—pollutants 5a, 10[a] and 14 Column B2—pollutants 5a, 10[a] and 14 Column D2—pollutants 1, 12, 17, 18, 21, 22, 29, 30, 32, 33, 37, 38, 42–44, 46, 48, 49, 54, 59, 66, 67, 68, 78–82, 85, 89, 90, 91, 93, 95, 96, 98
* * * * * * *	

[a] These freshwater selenium criteria are only applicable to the extent that the criteria under 40 CFR 131.38(b)(3) are not applicable (*i.e.*, they are only applicable in fresh waters).

* * * * *

■ 3. Section 131.38 is amended as follows:

■ a. Revise paragraph (b)(1) table footnotes "p" and "q";

■ b. Add paragraph (b)(3);

■ c. Revise paragraph (c)(3)(ii);

■ d. Add paragraphs (c)(3)(iv) and (v).

§ 131.38 Establishment of numeric criteria for priority toxic pollutants for the State of California.

* * * * *

(b)(1) * * *

Footnotes to Table in Paragraph (b)(1):

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p. The [Reserved] criterion referenced by this footnote does not supersede any selenium criterion set out in 40 CFR 131.36 for: Waters of the San Francisco Bay, upstream to and including Suisun Bay and the Sacramento-San Joaquin Delta; and waters of Salt Slough, Mud Slough (north) and the San Joaquin River, Sack Dam to the mouth of the Merced River. The criteria set out in 40 CFR 131.38(b)(3) apply to the salt and estuarine waters of the San Francisco Bay, upstream to and including Suisun Bay and the Sacramento-San Joaquin Delta, subject to 40 CFR 131.38(c)(3)(v). The State of California adopted and EPA approved a site specific criterion for the San Joaquin River, mouth of Merced to Vernalis; therefore, the criterion referenced by this footnote does not apply to these waters.

q. The 5 µg/L criterion referenced by this footnote does not supersede any selenium criterion set out in 40 CFR 131.36 for: Waters of the San Francisco Bay, upstream to and including Suisun Bay and the Sacramento-San Joaquin Delta; and waters of Salt Slough, Mud Slough (north) and the San Joaquin River, Sack Dam to Vernalis. The criteria set out in 40 CFR 131.38(b)(3) apply to the salt and estuarine waters of the San Francisco Bay, upstream to and including Suisun Bay and the Sacramento-San Joaquin Delta, subject to 40 CFR 131.38(c)(3)(v). The State of California adopted and EPA approved a site-specific criterion for the Grasslands Water District, San Luis National Wildlife Refuge, and the Los Banos State Wildlife Refuge; therefore, the criterion referenced by this footnote does not apply to these waters.

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(3) The selenium criteria in Table 1 to this paragraph (b)(3) apply to all the waters of San Francisco Bay upstream to and including Suisun Bay and the Sacramento-San Joaquin Delta where the salinity is greater than 1 part per thousand 95% or more of the time, subject to paragraph (c)(3)(v).

Table 1 to paragraph (b)(3): Selenium Water Quality Criteria for the Salt and Estuarine Waters of the San Francisco Bay, Upstream to and Including Suisun Bay and the Sacramento-San Joaquin Delta

Media Type	**Tissue**		**Water Column[1]**		
			Dissolved		**Particulate**
Criteria	**Fish Whole Body or Muscle**	**Clam**	**Chronic**	**Intermittent Exposure[2]**	**Chronic**
Magnitude	8.5 µg/g dw whole body or 11.3 µg/g dw muscle	15 µg/g dw	0.2 µg/L	$WQC_{int} = \dfrac{0.2\ \mu g/L - C_{bkgrnd}(1 - f_{int})}{f_{int}}$	1 µg/g dw
Duration	Instantaneous measurement	Instantaneous measurement	30 days	Number of days/month with an elevated concentration	30 days
Frequency	Not to be exceeded	Not to be exceeded	Not more than once in three years	Not more than once in three years	Not more than once in three years

[1] Dissolved and particulate water column values are based on total selenium (includes all oxidation states, i.e., selenite, selenate, organic selenium and any other forms) in water.

[2] C_{bkgrnd} is the average background selenium concentration in µg/L. f_{int} is the fraction of any 30-day period during which elevated selenium concentrations occur. f_{int} is assigned a value ≥ 0.033 (corresponding to one day).

Note 1: Salt and estuarine waters are defined here as those in which the salinity is greater than 1 part per thousand (ppt) 95% or more of the time.

Note 2: When these criteria are used to derive water quality-based effluent limitations for point sources, a translator of 1 must be used to convert dissolved selenium criteria values into total recoverable selenium values.

(c) * * *

(3) * * *

(ii) For waters in which the salinity is equal to or greater than 10 parts per thousand 95% or more of the time, the applicable criteria are the saltwater criteria in Column C.

* * * * *

(iv) Notwithstanding paragraphs (c)(3)(ii) and (iii) of this section, for waters of San Francisco Bay upstream to and including Suisun Bay and the Sacramento-San Joaquin Delta with salinity greater than 1 part per thousand 95% or more of the time, the selenium criteria provided in paragraph (b)(3) of this section are the only applicable selenium criteria, subject to paragraph (c)(3)(v).

(v) The criteria in paragraph (b)(3) of this section apply concurrently with any water quality criteria adopted by the state, except where California adopts site-specific selenium criteria for a segment of the estuary that EPA determines meet the requirements of Clean Water Act section 303(c) and 40 CFR part 131, in which case California's criteria will apply and not the criteria in paragraph (b)(3) of this section.

[FR Doc. 2016–16266 Filed 7–14–16; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

46 CFR Chapter I

[Docket No. USCG–2016–0669]

Draft Revisions to the Marine Safety Manual, Volume III, Parts B and C, Change-2

AGENCY: Coast Guard, DHS.

ACTION: Notice of availability with request for comments.

SUMMARY: The Coast Guard announces the availability of a draft update to the Marine Safety Manual (MSM), Volume III, Marine Industry Personnel, and the corresponding Commandant Change Notice that highlights the changes made

to that manual. MSM Volume III provides information and interpretations on international conventions and U.S. statutes and regulations relating to marine industry personnel. This draft Commandant Change Notice discusses the substantive changes to Parts B and C of MSM Volume III. The proposed changes are red-lined and each changed page is annotated with CH–2 in the footer. Additionally, we have created a document that provides a summary of each change. The Coast Guard seeks and will consider comments on these draft changes before issuing a final version of MSM Volume III.

DATES: Guidance documents discussed in this document should be available in the online docket within 3 business days of July 15, 2016. Comments must be received by the Coast Guard on or before September 13, 2016.

ADDRESSES: You may submit comments identified by docket number "USCG–2016–0669" using the Federal eRulemaking Portal at *http://www.regulations.gov.* See the "Public Participation and Request for Comments" portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: For information about this document call of email Lieutenant Commander Corydon Heard, U.S. Coast Guard; telephone 409–978–2704, email *Corydon.F.Heard@uscg.mil.*

SUPPLEMENTARY INFORMATION:

Background and Purpose

Volume III of the Marine Safety Manual (MSM) provides information and interpretations on international conventions and U.S. statutes and regulations relating to marine industry personnel. The last updates to Volume III of the MSM were released on July 30, 2014 (79 FR 45451, Aug. 5, 2014). This document announces updates to portions of Part B and C.

Specifically, substantive changes include: (1) Updated guidance to align with the Howard Coble Coast Guard and Maritime Transportation Act of 2014; (2) manning scales for towing vessels certificated under 46 CFR Subchapter M from the recently published Inspection of Towing Vessels final rule (81 FR 40003, June 20, 2016); and (3) various policy updates involving vessel manning.

In addition to red-lining proposed changes and annotating each changed page with CH–2 in the footer, we have created a change matrix identifying proposed changes. Both of these documents are available for viewing in the public docket.

It should be noted that the proposed revisions in this draft change are not intended to preempt or take the place of separate policy initiatives regarding specific decisions on appeal or future regulations. Future changes to the MSM may be released if the Coast Guard promulgates new regulations or issues appeal decisions, which may affect the guidance and information contained within the MSM.

Public Participation and Comments

We encourage you to submit comments (or related material) on our draft Commandant Change Notice 16000, CH–2 to the Marine Safety Manual, Volume III, Marine Industry Personnel, COMDTINST M16000.8B, which is in the docket and contains substantive changes to Parts B and C of MSM Volume III. We will consider all submissions and may adjust our final action based on your comments. If you submit a comment, please include the docket number for this notice, indicate the specific section of the Commandant Change Notice to which each comment applies, and provide a reason for each suggestion or recommendation.

We encourage you to submit comments through the Federal eRulemaking Portal at *http://www.regulations.gov.* If your material cannot be submitted using *http://www.regulations.gov,* contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions. Documents mentioned in this notice, and all public comments, are in our online docket at *http://www.regulations.gov* and can be viewed by following that Web site's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted or the Coast Guard publishes another document related to the draft Marine Safety Manual, Volume III, Parts B and C, Change-2.

We accept anonymous comments. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information you have provided. For more about privacy and the docket, you may review a Privacy Act notice regarding the Federal Docket Management System in the March 24, 2005, issue of the **Federal Register** (70 FR 15086).

This document is issued under authority of 5 U.S.C. 552(a).

Dated: July 11, 2016.

Verne B. Gifford,

Captain, U.S. Coast Guard, Director, Inspections and Compliance.

[FR Doc. 2016–16691 Filed 7–14–16; 8:45 am]

BILLING CODE 9110–04–P

Notices

Federal Register

Vol. 81, No. 136

Friday, July 15, 2016

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

AFRICAN DEVELOPMENT FOUNDATION

Public Quarterly Meeting of the Board of Directors

AGENCY: United States African Development Foundation.

ACTION: Notice of meeting.

SUMMARY: The U.S. African Development Foundation (USADF) will hold its quarterly meeting of the Board of Directors to discuss the agency's programs and administration.

DATES: The meeting date is Tuesday, July 19, 11 a.m. to 12 p.m. Executive session 12 p.m.

ADDRESSES: The meeting location is USADF, 1400 I St. NW., Suite 1000, Washington, DC 20005.

FOR FURTHER INFORMATION CONTACT: Aysha House, 202–233–8863.

Authority: Pub. L. 96–533 (22 U.S.C. 290h).

Dated: July 11, 2016.

Doris Mason Martin,

General Counsel.

[FR Doc. 2016–16730 Filed 7–14–16; 8:45 am]

BILLING CODE 6117–01–P

DEPARTMENT OF AGRICULTURE

Forest Service

Fishlake Resource Advisory Committee

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Fishlake Resource Advisory Committee (RAC) will meet in Richfield, Utah. The committee is authorized under the Secure Rural Schools and Community Self-Determination Act (the Act) and operates in compliance with the Federal Advisory Committee Act. The purpose of the committee is to improve collaborative relationships and to provide advice and recommendations to the Forest Service concerning projects and funding consistent with Title II of the Act. RAC information can be found at the following Web site: *http://cloudapps-usda-gov.force.com/FSSRS/RAC_Page?id=001t0000002JcvHAAS.*

DATES: The meeting will be held August 3, 2016 at 6 p.m. (MDT).

All RAC meetings are subject to cancellation. For status of meeting prior to attendance, please contact the person listed under **FOR FURTHER INFORMATION CONTACT.**

ADDRESSES: The meeting will be held at the Fishlake National Forest Supervisor's Office, 115 E 900 N., Richfield, Utah.

Written comments may be submitted as described under **SUPPLEMENTARY INFORMATION.** All comments, including names and addresses when provided, are placed in the record and are available for public inspection and copying. The public may inspect comments received at Fishlake National Forest Supervisor's Office. Please call ahead to facilitate entry into the building.

FOR FURTHER INFORMATION CONTACT: John Zapell, RAC Coordinator by phone at (435) 896–1070 or via email at *jzapell@fs.fed.us.*

Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8:00 a.m. and 8:00 p.m., Eastern Standard Time, Monday through Friday.

SUPPLEMENTARY INFORMATION: The purpose of the meeting is to:

1. Review, prioritize and recommend projects for funding.

The meeting is open to the public. The agenda will include time for people to make oral statements of three minutes or less. Individuals wishing to make an oral statement should request in writing by July 25, 2016 to be scheduled on the agenda. Anyone who would like to bring related matters to the attention of the committee may file written statements with the committee staff before or after the meeting. Written comments and requests for time to make oral comments must be sent to John Zapell, Designated Federal Officer, 115 E. 900 N., Richfield, Utah 84701; or by email to *jzapell@fs.fed.us,* or via facsimile to 435–896–9347.

Meeting Accommodations: If you are a person requiring reasonable accommodation, please make requests in advance for sign language interpreting, assistive listening devices, or other reasonable accommodation. For access to the facility or proceedings, please contact the person listed in the section titled **FOR FURTHER INFORMATION CONTACT.** All reasonable accommodation requests are managed on a case by case basis.

Dated: July 11, 2016.

Mel Bolling,

Forest Supervisor.

[FR Doc. 2016–16752 Filed 7–14–16; 8:45 am]

BILLING CODE 3411–15–P

DEPARTMENT OF AGRICULTURE

Forest Service

Cherokee Resource Advisory Committee Meeting

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Cherokee Resource Advisory Committee (RAC) will meet in Alcoa, Tennessee. The committee is authorized under the Secure Rural Schools and Community Self-Determination Act (the Act) and operates in compliance with the Federal Advisory Committee Act. The purpose of the committee is to improve collaborative relationships and to provide advice and recommendations to the Forest Service concerning projects and funding consistent with Title II of the Act. RAC information can be found at the following Web site: *http://www.fs.usda.gov/pts/.*

DATES: The meeting will be held August 24, 2016, at 1:00 p.m.

All RAC meetings are subject to cancellation. For status of meeting prior to attendance, please contact the person listed under **FOR FURTHER INFORMATION CONTACT.**

ADDRESSES: The meeting will be held at McGhee Tyson Airport—Airfield Maintenance Operations Center, 2950 Airfield Service Drive, Alcoa, Tennessee.

Written comments may be submitted as described under **SUPPLEMENTARY INFORMATION.** All comments, including names and addresses when provided, are placed in the record and are available for public inspection and copying. The public may inspect comments received at the Cherokee National Forest Supervisor's Office. Please call ahead to facilitate entry into the building.

FOR FURTHER INFORMATION CONTACT: Terry McDonald, RAC Coordinator, by phone at 423–476–9729 or via email at *twmcdonald@fs.fed.us.*

Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8:00 a.m. and 8:00 p.m., Eastern Standard Time, Monday through Friday.

SUPPLEMENTARY INFORMATION: The purpose of the meeting is to:

1. Discuss new committee membership outreach and recruiting efforts,
2. Review projects discussed at the last meeting, and
3. Recommend projects to the Forest Service for Cocke County and Monroe County, Tennessee.

The meeting is open to the public. The agenda will include time for people to make oral statements of three minutes or less. Individuals wishing to make an oral statement should request in writing by August 15, 2016, to be scheduled on the agenda. Anyone who would like to bring related matters to the attention of the committee may file written statements with the committee staff before or after the meeting. Written comments and requests for time to make oral comments must be sent to Terry McDonald, RAC Coordinator, 2800 Ocoee Street North, Cleveland, Tennessee 37312; by email to *twmcdonald@fs.fed.us,* or via facsimile to 423–476–9754.

Meeting Accommodations: If you are a person requiring reasonable accommodation, please make requests in advance for sign language interpreting, assistive listening devices, or other reasonable accommodation. For access to the facility or proceedings, please contact the person listed in the section titled **FOR FURTHER INFORMATION CONTACT.** All reasonable accommodation requests are managed on a case by case basis.

Dated: July 11, 2016.

D. JaSal Morris,

Forest Supervisor.

[FR Doc. 2016–16747 Filed 7–14–16; 8:45 am]

BILLING CODE 3411–15–P

CHEMICAL SAFETY AND HAZARD INVESTIGATION BOARD

Sunshine Act Meeting

TIME AND DATE: July 27, 2016, 1:00 p.m. EDT

PLACE: U.S. Chemical Safety Board, 1750 Pennsylvania Ave. NW., Suite 910, Washington, DC 20006.

STATUS: Open to the public.

MATTERS TO BE CONSIDERED: The Chemical Safety and Hazard Investigation Board (CSB) will convene a public meeting on July 27, 2016, starting at 1:00 p.m. EDT in Washington, DC, at the CSB offices located at 1750 Pennsylvania Avenue NW., Suite 910. The Board will provide an update on the 2016–2020 strategic plan, the status of Office of the Inspector General audits, open investigations, and the agency's action plan. The Board will also discuss financial and organizational updates. An opportunity for public comment will be provided.

Additional Information

The meeting is free and open to the public. If you require a translator or interpreter, please notify the individual listed below as the "Contact Person for Further Information," at least three business days prior to the meeting.

A conference call line will be provided for those who cannot attend in person. Please use the following dial-in number to join the conference: 1–888–466–9863, passcode 7176 237#.

The CSB is an independent federal agency charged with investigating accidents and hazards that result, or may result, in the catastrophic release of extremely hazardous substances. The agency's Board Members are appointed by the President and confirmed by the Senate. CSB investigations look into all aspects of chemical accidents and hazards, including physical causes such as equipment failure as well as inadequacies in regulations, industry standards, and safety management systems.

Public Comment

The time provided for public statements will depend upon the number of people who wish to speak. Speakers should assume that their presentations will be limited to three minutes or less, but commenters may submit written statements for the record.

Contact Person for Further Information

Hillary Cohen, Communications Manager, at *public@csb.gov* or (202) 446–8094. Further information about this public meeting can be found on the CSB Web site at: *www.csb.gov.*

Dated: July 12, 2016.

Kara A. Wenzel,

Acting General Counsel, Chemical Safety and Hazard Investigation Board.

[FR Doc. 2016–16901 Filed 7–13–16; 4:15 pm]

BILLING CODE 6350–01–P

DEPARTMENT OF COMMERCE

Bureau of the Census

Request for Nominations of Members To Serve on the Federal Economic Statistics Advisory Committee

AGENCY: Bureau of the Census, Commerce.

ACTION: Notice of request for nominations.

SUMMARY: The Secretary of Commerce is requesting nominations of individuals to the Federal Economic Statistics Advisory Committee. The Secretary will consider nominations received in response to this notice, as well as from other sources. The **SUPPLEMENTARY INFORMATION** section of this notice provides committee and membership criteria.

DATES: Please submit nominations by August 15, 2016.

ADDRESSES: Please submit nominations by Email to *james.r.spletzer@census.gov* (subject line "2016 FESAC Nominations"), or by letter submission to James R. Spletzer, Designated Federal Official, 2016 FESAC Nominations, Department of Commerce, U.S. Census Bureau, Room 5K175, 4600 Silver Hill Road, Washington, DC 20233. Nominations also maybe submitted via fax at 301–763–8609.

FOR FURTHER INFORMATION CONTACT: James R. Spletzer, Designated Federal Official, Department of Commerce, U.S. Census Bureau, Research and Methodology Directorate, Room 5K175, 4600 Silver Hill Road, Washington, DC 20233, telephone 301–763–4069, email: *james.r.spletzer@census.gov.* For TTY callers, please use the Federal Relay Service 1–800–877–8339.

SUPPLEMENTARY INFORMATION: The Federal Economic Statistics Advisory Committee (the "Committee") was established in accordance with the Federal Advisory Committee Act (Title 5, United States Code, Appendix 2). The following provides information about the Committee, membership, and the nomination process.

Objectives and Duties

1. The Committee is administratively housed at the Economics and Statistics Administration (ESA), U.S. Department of Commerce. The Committee advises the Directors of ESA's two statistical agencies, the Bureau of Economic Analysis (BEA) and the U.S. Census Bureau (Census), and the Commissioner of the Department of Labor's Bureau of Labor Statistics (BLS) (collectively called "the agencies") on statistical methodology and other technical matters related to the collection, tabulation, and analysis of federal economic statistics.

2. The Committee functions solely as an advisory committee to the senior officials of BEA, Census, and BLS in consultation with the Committee chairperson.

3. Important aspects of the Committee's responsibilities include, but are not limited to:

a. Recommending research to address important technical problems arising in federal economic statistics.

b. Identifying areas in which better coordination of the agencies activities would be beneficial.

c. Establishing relationships with professional associations with an interest in federal economic statistics.

d. Coordinating (in its identification of agenda items) with other existing academic advisory committees chartered to provide agency-specific advice for the purpose of avoiding duplication of effort.

4. The Committee reports to the Under Secretary for Economic Affairs who, as head of ESA, coordinates and collaborates with the agencies.

Membership

1. The Committee consists of approximately fourteen members who serve at the pleasure of the Secretary of Commerce.

2. Members are nominated by the Department of Commerce, in consultation with the agencies, under the coordination of the Under Secretary for Economic Affairs, and are appointed by the Secretary.

3. Committee members are economists, statisticians, survey methodologists, and behavioral scientists, and are chosen to achieve a balanced membership across those disciplines.

4. Members shall be prominent experts in their fields, and recognized for their scientific and professional achievements and objectivity.

a. Members serve as Special Government Employees (SGEs) and are subject to ethics rules applicable to SGEs.

b. Members serve three-year terms. Members may be reappointed to any number of additional three-year terms.

c. Should a Committee member be unable to complete a three-year term, a new member may be selected to complete that term for the duration of the time remaining or begin a new term of three years.

d. The agencies, by consensus agreement, shall appoint the chairperson annually from the Committee membership. Chairpersons shall be permitted to succeed themselves.

Miscellaneous

1. Members of the Committee will not be compensated for their services, but will be reimbursed for travel expenses upon request.

2. The Committee meets approximately twice a year, budget permitting. Special meetings may be called when appropriate.

Nomination Process

1. Nominations are requested as described above.

2. Nominees must be economists, statisticians, survey methodologists, and behavioral scientists and will be chosen to achieve a balanced membership across those disciplines. Nominees must be prominent experts in their fields, and recognized for their scientific and professional achievements and objectivity. Such knowledge and expertise are needed to advise the agencies on statistical methodology and other technical matters related to the collection, tabulation, and analysis of federal economic statistics.

3. Individuals, groups, and/or organizations may submit nominations on behalf of an individual candidate. A summary of the candidate's qualifications (resumé or curriculum vitae) must be included along with the nomination letter. Nominees must be able to actively participate in the tasks of the Committee including, but not limited to, regular meeting attendance, committee meeting discussant responsibilities, review of materials, as well as participation in conference calls, webinars, working groups, and special committee activities.

4. The Department of Commerce is committed to equal opportunity in the workplace and seeks diverse Committee membership.

Dated: July 8, 2016.

John H. Thompson,

Director, Bureau of the Census.

[FR Doc. 2016–16758 Filed 7–14–16; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–924]

Polyethylene Terephthalate Film, Sheet, and Strip From the People's Republic of China: Rescission of Antidumping Administrative Review; 2014–2015

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce ("the Department") is rescinding the administrative review of the antidumping duty order on polyethylene terephthalate film, sheet, and strip ("PET film") from the People's Republic of China ("PRC") for the period November 1, 2014, through October 31, 2015.

DATES: *Effective Date:* July 15, 2016.

FOR FURTHER INFORMATION CONTACT: Jonathan Hill, Office IV, Enforcement & Compliance, International Trade Administration, Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–3518.

SUPPLEMENTARY INFORMATION:

Background

On January 7, 2016, based on a timely request for review by Mitsubishi Polyester Film, Inc. and SKC, Inc. (collectively, "Petitioners"), the Department published in the **Federal Register** a notice of initiation of an administrative review of the antidumping duty order on PET film from the PRC with respect to four companies covering the period November 1, 2014 through October 31, 2015.[1] On February 29, 2016, Petitioners withdrew their request for an administrative review of all of the companies for which the Department initiated a review.[2]

Rescission of Review

Pursuant to 19 CFR 351.213(d)(1), the Department will rescind an administrative review, in whole or in part, if the party that requested the review withdraws its request within 90 days of the publication of the notice of initiation of the requested review. In this case, Petitioners timely withdrew their review request by the 90-day deadline, and no other party requested an administrative review of the antidumping duty order. As a result, we are rescinding the administrative review of the antidumping duty order on PET film from the PRC for the period November 1, 2014, through October 31, 2015, in its entirety.

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[1] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 81 FR 736 (January 7, 2016) ("*Initiation Notice*").

[2] *See* Letter from Petitioners to the Secretary of Commerce "Polyethylene Terephthalate (PET) Film, Sheet, and Strip from the People's Republic of China: Withdrawal of Request for Antidumping Duty Administrative Review," dated February 29, 2016.

Assessment

The Department will instruct U.S. Customs and Border Protection ("CBP") to assess antidumping duties on all appropriate entries. Because the Department is rescinding this administrative review in its entirety, the entries to which this administrative review pertained shall be assessed antidumping duties that are equal to the cash deposits of estimated antidumping duties required at the time of entry, or withdrawal from warehouse, for consumption, in accordance with 19 CFR 351.212(c)(1)(i). The Department intends to issue appropriate assessment instructions to CBP within 15 days after the publication of this notice.

Notification to Importers

This notice serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Department's presumption that reimbursement of the antidumping duties occurred and the subsequent assessment of doubled antidumping duties.

Administrative Protective Orders

This notice also serves as a final reminder to parties subject to administrative protective order ("APO") of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305, which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return or destruction of APO materials, or conversion to judicial protective order, is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

Notification to Interested Parties

This notice is issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Tariff Act of 1930, as amended, and 19 CFR 351.213(d)(4).

Dated: July 11, 2016.

Christian Marsh,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2016–16807 Filed 7–14–16; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–552–802]

Certain Frozen Warmwater Shrimp From the Socialist Republic of Vietnam: Partial Rescission of Antidumping Duty Administrative Review; 2015–2016

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce ("the Department") is rescinding the administrative review, in part, of the antidumping duty order on certain frozen warmwater shrimp from the Socialist Republic of Vietnam ("Vietnam") for the period February 1, 2015 through January 31, 2016.

DATES: Effective July 15, 2016.

FOR FURTHER INFORMATION CONTACT: Irene Gorelik, AD/CVD Operations, Office V, Enforcement and Compliance, International Trade Administration, Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–6905.

SUPPLEMENTARY INFORMATION:

Background

On April 7, 2016, based on timely requests for review for 62 companies by Ad Hoc Shrimp Trade Action Committee ("Petitioner"),[1] 193 companies by the American Shrimp Processors Association ("ASPA"),[2] and various Vietnamese companies,[3] the Department published in the **Federal Register** a notice of initiation of an administrative review of the antidumping duty order on certain frozen warmwater shrimp from Vietnam covering the period February 1, 2015, through January 31, 2016.[4]

On June 30, 2016, Quoc Viet and Thong Thuan withdrew their respective requests for administrative review.[5] On July 1, 2016, Petitioner withdrew its request for an administrative review for 20 companies, and their various name iterations, as listed in the *Initiation Notice.*[6] On July 1, 2016, ASPA withdrew its request for an administrative review for 22 companies and their various name iterations, as listed in the *Initiation Notice.*[7] On July 1, 2016, VASEP withdrew its request for an administrative review of 17 companies and their various name iterations, as listed in the *Initiation Notice.*[8] No other party requested a review of these exporters. On July 6, 2016, Petitioner, ASPA, and the Minh Phu Group withdrew their respective requests for administrative review of the Minh Phu Group, which the Department intends to rescind in a separate notice.

Partial Rescission of Review

Pursuant to 19 CFR 351.213(d)(1), the Department will rescind an administrative review, in whole or in part, if the party that requested the review withdraws its request within 90 days of the publication of the notice of initiation of the requested review. Because Petitioner, ASPA, and the individual companies all withdrew their requests for administrative review within 90 days of the date of publication of the *Initiation Notice,* and no other interested party requested a review of these companies,[9] the Department is rescinding this review with respect to the companies with no remaining review requests identified in Appendix 1, in accordance with 19 CFR 351.213(d)(1).

Assessment

The Department will instruct U.S. Customs and Border Protection ("CBP") to assess antidumping duties on all appropriate entries at a rate equal to the cash deposit of estimated antidumping duties required at the time of entry, or withdrawal from warehouse, for consumption, during the period February 1, 2015, through January 31, 2016, in accordance with 19 CFR 351.212(c)(1)(i). The Department intends to issue appropriate assessment instructions to CBP 15 days after the publication of this notice in the **Federal Register**, if appropriate.

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[1] *See* Petitioner's Request for Administrative Review, dated February 29, 2016.

[2] *See* ASPA's Request for Administrative Review, dated February 29, 2016.

[3] *See* VASEP's submission, "Request for Administrative Review (02/01/15–01/31/16)," dated February 29, 2016. *See also* Quoc Viet Seaproducts Processing Trading and Import-Export Co., Ltd.'s ("Quoc Viet") and Thong Thuan Company Limited's ("Thong Thuan") combined submission dated February 29, 2016.

[4] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 81 FR 20324 (April 7, 2016) ("*Initiation Notice*").

[5] *See* Quoc Viet and Thong Thuan's Submission re; "Withdrawal of Request for Administrative Review," dated June 30, 2016.

[6] *See* Petitioners' Submissions re; "Domestic Producers' Partial Withdrawal of Review Requests," dated July 1, 2016.

[7] *See* ASPA's Submissions re; "Domestic Producers' Partial Withdrawal of Review Requests," dated July 1, 2016.

[8] *See* VASEP's Submission re; "Partial Withdrawal of Review Requests," dated July 1, 2016.

[9] While Petitioner and ASPA withdrew their respective review requests of Tan Phong Phu Seafood Co., Ltd., VASEP did not withdraw its review request on behalf of this company; thus, we are not rescinding the review with respect to Tan Phong Phu Seafood Co., Ltd., as there remains an active review request for it on the record.

Notifications

This notice serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Department's presumption that reimbursement of the antidumping duties occurred and the subsequent assessment of doubled antidumping duties.

This notice also serves as a final reminder to parties subject to administrative protective order ("APO") of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return or destruction of APO materials, or conversion to judicial protective order, is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

This notice is issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Tariff Act of 1930, as amended, and 19 CFR 351.213(d)(4).

Dated: July 11, 2016.

Christian Marsh,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

Appendix I—Companies Rescinded From Review

1.—Bac Lieu Fisheries Joint Stock Company
  —Bac Lieu Fisheries Joint Stock Company ("Bac Lieu")
  —Bac Lieu Fisheries Joint Stock Company ("Bac Lieu Fis")
2.—Ca Mau Seafood Joint Stock Company ("Seaprimexco Vietnam")
  —Ca Mau Seafood Joint Stock Company ("Seaprimexco")
  —Ca Mau Seafood Joint Stock Company ("SEAPRIMEXCO")
  —Minh Hai Sea Products Import Export Company ("Seaprimex Co")
  —Seaprimexco
  —Seaprimexco Vietnam
3.—Camau Seafood Factory No.5
  —Camau Seafood Factory No.4
  —Camau Frozen Seafood Processing ImportExport Corporation ("CAMIMEX")
  —Camau Frozen Seafood Processing Import Export Corporation ("Camimex")
  —Camau Frozen Seafood Processing Import Export Corp. (CAMIMEX-FAC 25)
  —Camau Frozen Seafood Processing Import-Export Corporation ("CAMIMEX")
  —Camau Frozen Seafood Processing Import Export Corporation ("Camimex")
  —Ca Mau Frozen Seafood Processing Import Export Corporation ("CAMIMEX")
4.—Camau Seafood and Service Joint Stock Company ("CASES")
  —Camau Seafood Processing and Service Jointstock Corporation ("CASES")
  —Camau Seafood Processing and Service Joint-Stock Company ("CASES")
  —Camau Seafood Processing and Service Joint Stock Corporation (and its affiliates, Kien Giang Branch—Camau Seafood Processing & Service Joint Stock Corporation, collectively "CASES")
5. Can Tho Import Export Fishery Limited Company ("CAFISH")
6.—Cuu Long Seaproducts Company ("Cuu Long Seapro")
  —Cuulong Seaproducts Company ("Cuulong Seapro")
  —Cuulong Seaproducts Company ("Cuu Long Seapro")
  —CL Fish Co., Ltd. (Cuu Long Fish Company)
7.—Hai Viet Corporation (HAVICO)
  —Hai Viet Corporation ("HAVICO")
8.—Minh Hai Export Frozen Seafood Processing Joint-Stock Company ("Minh Hai Jostoco")
  —Minh Hai Export Frozen Seafood Processing JointStock Company ("Minh Hai Jostoco")
9.—Minh Hai Joint-Stock Seafoods Processing Company (Seaprodex Minh Hai) (Sea Minh Hai)
  —Minh Hai Joint-Stock Seafoods Processing Company ("Seaprodex Minh Hai")
  —Sea Minh Hai
  —Seaprodex Minh Hai (Minh Hai Joint Stock Seafoods Processing Co.)
  —Seaprodex Minh Hai
10. Ngoc Tri Seafood Joint Stock Company
11.—Nha Trang Seaproduct Company (and its affiliates NT Seafoods Corporation, Nha Trang Seafoods—F.89 Joint Stock Company, NTSF Seafoods Joint Stock Company (collectively "Nha Trang Seafoods Group")
  —NTSF Seafoods Joint Stock Company ("NTSF Seafoods") (Nha Trang Seafoods F89 Joint Stock Company) (Nha Trang Seaproduct Company) (NT Seafoods Corporation)
  —Nha Trang Seaproduct Company ("Nha Trang Seafoods")
12.—Quoc Viet Seaproducts Processing Trading and Import-Export Co., Ltd.
  —Quoc Viet Seaproducts Processing Trade and Import-Export Co., Ltd. ("Quoc Viet Co. Ltd.")
13.—Sao Ta Foods Joint Stock Company (Sao Ta Seafood Factory) (FIMEX VN)
  —Sao Ta Foods Joint Stock Company ("FIMEX VN") (and its factory "Sao Ta Seafoods Factory")
  —Fimex VN
  —Sao Ta Foods Joint Stock Company ("Fimex VN")
  —Sao Ta Seafood Factory
14. Seavina Joint Stock Company
15.—Soc Trang Aquatic Products and General Import Export Company ("Stapimex")
  —Soc Trang Seafood Joint Stock Company ("STAPIMEX")
  —Soc Trang Seafood Joint Stock Company ("Stapimex")
16.—Cong Ty Tnhh Thong Thuan (Thong Thuan)
  —Thong Thuan Company Limited
  —Thong Thuan Company
17.—Thong Thuan Seafood Company Limited
  —Thong Thuan—Cam Ranh Seafood Joint Stock Company
18.—Thuan Phuoc Seafoods and Trading Corporation
  —Thuan Phuoc Seafoods and Trading Corporation ("Thuan Phuoc Corp")
  —Thuan Phuoc Seafoods and Trading Corporation and its separate factories Frozen Seafood Factory No. 32, Seafoods and Foodstuff Factory, and My Son Seafoods Factory (collectively "Thuan Phuoc Corp.")
  —Seafoods and Foodstuff Factory
  —My Son Seafoods Factory
  —Frozen Seafoods Factory No. 32
19.—Viet Foods Co., Ltd.
  —Viet Foods Co., Ltd. ("Viet Foods")
  —Nam Hai Foodstuff and Export Company Ltd
20.—Vietnam Clean Seafood Corporation
  —Vietnam Clean Seafood Corporation ("Vina Cleanfood")
  —Vietnam Clean Seafood Corporation (VINA Cleanfood)
21.—Viet I-Mei Frozen Foods Co., Ltd.
  —Viet I-Mei Frozen Foods Co. Ltd ("Viet I-Mei")

[FR Doc. 2016–16804 Filed 7–14–16; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–552–820]

Antidumping Duty Investigation of Circular Welded Carbon-Quality Steel Pipe From the Socialist Republic of Vietnam: Amended Affirmative Preliminary Determination

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Department) is amending the preliminary determination of the antidumping duty (AD) investigation of circular welded carbon-quality steel pipe (CWP) from the Socialist Republic of Vietnam (Vietnam) to correct significant ministerial errors.

DATES: Effective July 15, 2016.

FOR FURTHER INFORMATION CONTACT: Nancy Decker or Andrew Huston, AD/

CVD Operations, Office VII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–0196 or (202) 482–4261, respectively.

SUPPLEMENTARY INFORMATION:

Background

On June 8, 2016, the Department published its affirmative preliminary determination that CWP from Vietnam is being, or is likely to be, sold in the United States at less than fair value, as provided by section 733 of the Tariff Act of 1930, as amended (the Act).[1] The Department disclosed the calculations performed on June 6, 2016. Therefore, the deadline for submitting ministerial error allegations under 19 CFR 351.224(c)(2) was June 13, 2016.

The petitioners [2] timely filed comments alleging significant ministerial errors in the margin calculated for Vietnam Haiphong Hongyuan Machinery Manufactory Co., Ltd. (Hongyuan).[3] In addition, SeAH Steel VINA Corporation (SeAH) timely filed comments alleging ministerial errors in its margin calculation.[4]

Scope of the Investigation

For a full description of the scope of this investigation, *see* "Scope of Investigation" at Appendix II of the *Preliminary Determination.*

Analysis of Significant Ministerial Error Allegations

The Department will analyze any comments received and, if appropriate, correct any significant ministerial error by amending the preliminary determination according to 19 CFR 351.224(e). A ministerial error is defined in 19 CFR 351.224(f) as "an error in addition, subtraction, or other arithmetic function, clerical error resulting from inaccurate copying, duplication, or the like, and any other similar type of unintentional error which the Secretary considers ministerial." Further, a significant ministerial error is defined in 19 CFR 351.224(g) as a ministerial error, the correction of which, singly or in combination with other errors, would result in: (1) A change of at least five absolute percentage points in, but not less than 25 percent of, the weighted-average dumping margin calculated in the original (erroneous) preliminary determination; or (2) a difference between a weighted-average dumping margin of zero (or *de minimis*) and a weighted-average dumping margin of greater than *de minimis,* or vice versa.

In accordance with 19 CFR 351.224(e) and (g)(2), the Department is amending the *Preliminary Determination* to reflect the corrections of significant ministerial errors in Hongyuan's margin calculation. However, as the ministerial errors alleged by SeAH are not significant in accordance with 19 CFR 351.224(g), the Department has not analyzed SeAH's comments, and is not amending SeAH's margin calculation. As a result of amending Hongyuan' margin, the Department is also revising the margin for the separate rate company.[5]

Ministerial Error Allegations

For a complete analysis of the ministerial error allegations, *see* the Ministerial Error Memorandum.[6]

Amended Preliminary Determination

We are correcting the preliminary dumping margin for Hongyuan. Consequently, we are also amending the preliminary separate rate for Hoa Phat Steel Pipe Co. (Hoa Phat). SeAH's preliminary dumping margin is unchanged.

Exporter	Producer	Weighted-average dumping margin (percent)
Vietnam Haiphong Hongyuan Machinery Manufactory Co., Ltd	Vietnam Haiphong Hongyuan Machinery Manufactory Co., Ltd	2.32
Hoa Phat Steel Pipe Co	Hoa Phat Steel Pipe Co	2.32
SeAH Steel VINA Corporation	SeAH Steel VINA Corporation	0.00
Vietnam-Wide Entity		113.18

Amended Cash Deposits and Suspension of Liquidation

The collection of cash deposits and suspension of liquidation will be revised according to the rates calculated in this amended preliminary determination. Because Hongyuan's and Hoa Phat's amended rates are now above *de minimis,* we will direct U.S. Customs and Border Protection (CBP) to suspend liquidation of entries of CWP from Vietnam produced, as described in the scope of the section, which were produced and exported by these companies entered, or withdrawn from warehouse, for consumption. Because the correction of the errors for Hongyuan effectively results in increased cash deposit rates for Hongyuan and Hoa Phat, the revised rates calculated for Hongyuan and Hoa Phat will be effective on the date of publication of this notice in the **Federal Register**. Parties will be notified of this determination, in accordance with sections 733(d) and (f) of the Act.

International Trade Commission Notification

In accordance with section 733(f) of the Act, we notified the International Trade Commission of our amended preliminary determination.

Notification to Interested Parties

The Department intends to disclose calculations performed in connection with this amended preliminary determination within five days of the date of publication of this notice in accordance with 19 CFR 351.224(b).

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[1] *See Circular Welded Carbon-Quality Steel Pipe From the Socialist Republic of Vietnam: Affirmative Preliminary Determination of Sales at Less Than Fair Value and Postponement of Final Determination,* 81 FR 36884 (June 8, 2016) (*Preliminary Determination*).

[2] The petitioners are Bull Moose Tube Company; EXLTUBE; Wheatland Tube, a division of JMC Steel Group; and Western Tube and Conduit.

[3] *See* the petitioners' June 13, 2016, letter.

[4] *See* SeAH's June 13, 2016, letter.

[5] *See* Memorandum to Gary Taverman, Associate Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, "Ministerial Error Memorandum for the Affirmative Preliminary Determination of the Antidumping Duty Investigation of Circular Welded Carbon-Quality Steel Pipe From the Socialist Republic of Vietnam," dated concurrently with this notice, for the analysis performed (Ministerial Error Memorandum). This memorandum is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov,* and is available to all parties in the Department's Central Records Unit in Room B8024 of the Department of Commerce building.

[6] *Id.*

This amended preliminary determination is issued and published in accordance with sections 733(f) and 777(i)(1) of the Act and 19 CFR 351.224(e).

Dated: July 6, 2016.

Ronald K. Lorentzen,

Acting Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2016–16806 Filed 7–14–16; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–489–805]

Certain Pasta From Turkey: Preliminary Rescission of Antidumping Duty New Shipper Review

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (the Department) is conducting a new shipper review (NSR) of the antidumping duty order on certain pasta (pasta) from Turkey. The NSR covers one exporter and producer of subject merchandise, Durum Gida Sanayi ve Ticaret A.S. (Durum). The period of review (POR) is July 1, 2014 through June 30, 2015. The Department preliminarily determines that Durum did not make a *bona fide* sale during the POR; therefore, we are preliminarily rescinding this NSR. Interested parties are invited to comment on the preliminary results of this review.

DATES: Effective July 15, 2016.

FOR FURTHER INFORMATION CONTACT: Fred Baker or Robert James, AD/CVD Operations, Office VI, Enforcement and Compliance, International Trade Administration, Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–2924 and (202) 482–0649, respectively.

SUPPLEMENTARY INFORMATION:

Background

On September 2, 2015, the Department published a notice of initiation of a new shipper review of the antidumping duty order on pasta from Turkey.[1] The Department subsequently issued initial and supplemental questionnaires to Durum, and received timely responses thereto.

The Department has exercised its discretion to toll all administrative deadlines due to the closure of the Federal Government because of Snowstorm "Jonas." Thus, all of the deadlines in this segment of the proceeding were extended by four business days. The revised deadline for the preliminary results of this review, after the four business-day extension, was February 29, 2016.[2] However, on February 29, 2016, the Department extended the time period for issuing the preliminary results of this NSR by 106 days, until June 14, 2016.[3] We extended it again by 14 days on June 8, 2016, until June 28, 2016.[4]

Scope of the Order

Imports covered by this review are shipments of certain non-egg dry pasta in packages of five pounds (2.27 kilograms) or less, whether or not enriched or fortified or containing milk or other optional ingredients such as chopped vegetables, vegetable purees, milk, gluten, diastases, vitamins, coloring and flavorings, and up to two percent egg white.

For a full description of the scope of the order, *see* the memorandum from Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, to Paul Piquado, Assistant Secretary for Enforcement and Compliance, "Decision Memorandum for Certain Pasta from Turkey: Preliminary Results of New Shipper Review" (Preliminary Decision Memorandum), which is dated concurrently with this notice, and is hereby incorporated by reference.[5]

Methodology

The Department is conducting this review in accordance with section 751(a)(2)(B) of the Tariff Act of 1930, as amended (the Act) and 19 CFR 351.214. For a full description of the methodology underlying our conclusions, *see* the Preliminary Decision Memorandum, which is hereby adopted by this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov* and is available in the Central Records Unit, Room B8024 of the main Department of Commerce building. In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/*. The signed Preliminary Decision Memorandum and the electronic version of the Preliminary Decision Memorandum are identical in content.

Preliminary Rescission of the Antidumping New Shipper Review of Durum

As discussed in the *Bona Fide* Sales Analysis Memorandum,[6] the Department preliminarily finds that the sale made by Durum serving as the basis for this review is not a *bona fide* sale. The Department reached this conclusion based on the totality of the circumstances surrounding the reported sale, including the sales price, the number of sales that Durum reported, the importer's inability to prove that it had received payment from its U.S. customers, and the fact that the record fails to establish that the U.S. importer realized a profit on its re-sale of the subject merchandise.

Because the non-*bona fide* sale was the only reported sale of subject merchandise during the POR, we find there are no reviewable transactions during this new shipper period of review. Accordingly, we are preliminarily rescinding this NSR.[7] Because the factual information used in our *bona fides* analysis of Durum's sale involves business proprietary information, for a full discussion of the basis for our preliminary determination *see* the *Bona Fide* Sales Analysis Memorandum.

Public Comment

Interested parties may submit case briefs no later than 30 days after the date of publication of the preliminary results of review.[8] Rebuttals to case briefs may be filed no later than five days after the briefs are filed. All rebuttal comments must be limited to comments raised in the case briefs.[9]

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[1] *See Certain Pasta From Turkey: Initiation of Antidumping Duty New Shipper Review,* 80 FR 53112 (September 2, 2015) (*Initiation Notice*).

[2] *See* Memorandum to the Record from Ron Lorentzen, Acting Assistant Secretary for Enforcement & Compliance, regarding "Tolling of Administrative Deadlines as a Result of the Government Closure during Snowstorm Jonas," dated January 27, 2016.

[3] *See* Memorandum to Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, "Certain Pasta from Turkey: Extension of Deadline for Preliminary Results of Antidumping Duty New Shipper Review," dated February 29, 2016.

[4] *See* Memorandum to Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, "Certain Pasta from Turkey: Extension of Deadline for Preliminary Results of Antidumping Duty New Shipper Review," dated June 8, 2016.

[5] A list of the topics discussed in the Preliminary Decision Memorandum appears in Appendix I of this notice.

[6] *See* Memorandum from Fred Baker, International Trade Analyst, Office VI AD/CVD Operations, to Scot Fullerton, Director, Office VI, AD/CVD Operations entitled "2014–2015 Antidumping Duty New Shipper Review of Certain Pasta From Turkey: Preliminary *Bona Fide* Sales Analysis for Durum Gida Sanayi ve Ticaret A.S.," (*Bona Fide* Sales Analysis Memorandum) dated concurrently with and hereby adopted by this notice.

[7] *See* 19 CFR 351.213(d)(3).

[8] *See* 19 CFR 351.309(c).

Interested parties who wish to request a hearing must submit a written request to the Assistant Secretary for Enforcement & Compliance, U.S. Department of Commerce, within 30 days after the date of publication of this notice.[10] Requests should contain the party's name, address, and telephone number, the number of participants, and a list of the issues to be discussed. Oral argument presentations will be limited to issues raised in the briefs. If a request for a hearing is made, the Department intends to hold the hearing at the U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230, at a date and time to be determined.[11] Parties should confirm by telephone the date, time, and location of the hearing two days before the scheduled date.

All submissions, with limited exceptions, must be filed electronically using ACCESS. An electronically filed document must be received successfully in its entirety by the Department's electronic records system, ACCESS, by 5 p.m. Eastern Time (ET) on the due date. Documents excepted from the electronic submission requirements must be filed manually (*i.e.,* in paper form) with the APO/Dockets Unit in Room 18022, and stamped with the date and time of receipt by 5 p.m. ET on the due date.[12]

The Department intends to issue the final results of this NSR, which will include the results of its analysis of issues raised in any briefs received, no later than 90 days after the date these preliminary results of review are issued pursuant to section 751(a)(2)(B) of the Act.

Assessment Rates

If the Department proceeds to a final rescission of Durum's NSR, the assessment rate to which Durum's shipments will be subject will not be affected by this review. If the Department does not proceed to a final rescission of this new shipper review, pursuant to 19 CFR 351.212(b)(1), we will calculate importer-specific (or customer-specific) assessment rates based on the final results of this review.

Cash Deposit Requirements

Effective upon publication of the final rescission or the final results of this NSR, the Department will instruct CBP to discontinue the option of posting a bond or security in lieu of a cash deposit for entries of Durum's subject merchandise. If the Department proceeds to a final rescission of this NSR, Durum's cash deposit rate will continue to be the all-others rate. If the Department issues final results for this NSR, the Department will instruct CBP to collect cash deposits, effective upon the publication of the final results, at the rates established therein.

Notification to Importers

This notice also serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Department's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

We are issuing and publishing these results in accordance with sections 751(a)(2)(B) and 777(i)(1) of the Act.

Dated: June 28, 2016.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

Appendix I

List of Sections in the Preliminary Decision Memorandum

1. Summary
2. Background
3. Scope of the Order
4. Discussion of the Methodology
5. Conclusion

[FR Doc. 2016–16694 Filed 7–14–16; 8:45 am]

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[9] *See* 19 CFR 351.309(d).

[10] *See* 19 CFR 351.310(c).

[11] *See* 19 CFR 351.310(d).

[12] *See Antidumping and Countervailing Duty Proceedings: Electronic Filing Procedures; Administrative Protective Order Procedures,* 76 FR 39263 (July 6, 2011).

DEPARTMENT OF COMMERCE

International Trade Administration

[A–201–830]

Carbon and Certain Alloy Steel Wire Rod From Mexico: Notice of Court Decision Not in Harmony With Amended Final Determination and Notice of Second Amended Final Determination

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: On December 22, 2014, the United States Court of International Trade (CIT) entered its final judgment in *Deacero III,*[1] sustaining the Department of Commerce's (the Department) negative circumvention determination from the First Remand Results as it relates to the antidumping duty order on carbon and certain alloy steel wire rod from Mexico.[2] Consistent with the decision of the United States Court of Appeals for the Federal Circuit (Federal Circuit) in *Timken,*[3] as clarified by *Diamond Sawblades,*[4] the Department issued the *Amended Final Determination*[5] notifying the public that the final judgment of the CIT in this case was not in harmony with the Department's finding in the *Final Determination.*[6] In the *Amended Final Determination,* the Department found, under protest, that, pursuant to section 781(c) of the Tariff Act of 1930, as amended (the Act) and 19 CFR 351.225, Deacero's entries of wire rod with an actual diameter of 4.75 millimeters (mm) to 5.00 mm (also referred to in this notice as small diameter wire rod) did not constitute circumvention of the *Order.* On April 5, 2016, the Federal Circuit reversed the CIT's holding in *Deacero III.*[7] In its holding, the Federal Circuit reinstated the Department's original finding from the *Final Determination* that Deacero's shipments of small diameter wire rod to the United States constitute a minor alteration circumvention of the *Order.*[8]

DATES: Effective April 15, 2016.

FOR FURTHER INFORMATION CONTACT: Eric B. Greynolds, or James Terpstra. AD/

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[1] *See Deacero S.A.P.I. de C.V. and Deacero USA, Inc.* v. *United States and Arcelormittal USA LLC, Gerdau Ameristeel U.S. Inc., Evraz Rocky Mountain Steel, and Nucor Corporation,* Court No. 12–00345, Slip Op. 14–151 (December 22, 2014) (*Deacero III*).

[2] *See* Final Results of Redetermination Pursuant to *Deacero S.A. de C.V. and Deacero USA Inc.* v. *United States and Arcelormittal USA LLC, Gerdau Ameristeel U.S. Inc., Evraz Rocky Mountain Steel, and Nucor Corporation,* Court No. 12–00345; Slip Op. 13–126 (CIT 2013) (January 29, 2014) (First Remand Results); *Notice of Antidumping Duty Orders: Carbon and Certain Alloy Steel Wire Rod from Brazil, Indonesia, Mexico, Moldova, Trinidad and Tobago, and Ukraine,* 67 FR 65945 (October 29, 2002) (*Order*).

[3] *See Timken Co.* v. *United States,* 893 F.2d 337 (Fed. Cir. 1990) (*Timken*).

[4] *See Diamond Sawblades Mfrs. Coalition* v. *United States,* 626 F.3d 1374 (Fed. Cir. 2010) (*Diamond Sawblades*).

[5] *See Carbon and Certain Alloy Steel Wire Rod From Mexico: Notice of Court Decision Not in Harmony With Final Results and Notice of Amended Final Determination,* 80 FR 44326 (July 27, 2015) (*Amended Final Determination*).

[6] *See Carbon and Certain Alloy Steel Wire Rod From Mexico: Affirmative Final Determination of Circumvention of the Antidumping Duty Order,* 77 FR 59892 (October 1, 2012) (*Final Determination*) and accompanying Issues and Decision Memorandum (Final Decision Memorandum).

[7] *See Deacero S.A.de C.V.* v. *United States,* 817 F.3d 1332 (Fed. Cir. 2016) (*Deacero IV*).

[8] *Id.* at 12.

CVD Operations, Office III, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–6071, (202) 482–3965, respectively.

SUPPLEMENTARY INFORMATION:

Background

On October 1, 2012, the Department issued the *Final Determination* in which it determined that Deacero's entries of wire rod with an actual diameter of 4.75 mm to 5.00 mm constitute a minor alteration circumvention of the *Order*.[9] Deacero challenged the Department's determination. Upon review, the CIT remanded the *Final Determination*, holding that the Department improperly determined that Deacero's entries of small diameter wire rod were inside the scope of the *Order* despite the fact that small diameter wire rod was commercially available before the investigation and Petitioners[10] "consciously chose to limit the *Order's* reach to certain steel products 5.00 mm or more, but less than 19.00 mm in solid cross-sectional diameter."[11] On remand, based on the Court's reasoning, the Department found that there was no alternative but to change the results of the anti-circumvention determination and find that Deacero's entries of wire rod with an actual diameter of 4.75 mm to 5.00 mm were not within the scope of the *Order*.[12]

In *Deacero II*, the Court held that although the Department ultimately reached a supportable result in the First Remand Results, remand was nonetheless necessary because the Department arrived at the result by misinterpreting *Deacero I*.[13] Therefore, in *Deacero II*, the Court instructed the Department to explain whether it seeks the Court's leave to revisit the issue of commercial availability.[14]

In the Second Remand Results, the Department continued to respectfully disagree with the Court that the "commercial availability" of a product in the country in question, in a third country or in the United States bars the Department from reaching an affirmative anti-circumvention determination under the minor alteration provision of the statute.[15] For these same reasons, the Department did not request a remand to further consider "commercial availability" in the context of this minor alteration proceeding. On December 22, 2014, the CIT entered final judgment sustaining the First Remand Results.[16] Accordingly, July 27, 2015, the Department issued the *Amended Final Determination* in which it found that Deacero's entries of small diameter wire rod were not circumventing the *Order* and, thus, were not subject to antidumping (AD) duties.[17] In the *Amended Final Determination*, the Department indicated that it would instruct Customs and Border Protection (CBP) to continue the suspension of liquidation of the subject merchandise, but set the cash deposit rate for Deacero's entries of wire rod with an actual diameter of 4.75 mm up to 5.00 mm to zero pending a final and conclusive court decision.[18] Further, in the *Amended Final Determination*, the Department stated that for any AD duties which were deposited for Deacero's entries of wire rod with an actual diameter of 4.75 mm up to 5.00 mm entered from January 1, 2015, to July 27, 2015, the publication date of the *Amended Final Determination*, the Department would instruct CBP to refund the cash deposit upon request but continue to suspend the entries at a zero cash deposit rate.[19]

In *Deacero IV*, the Federal Circuit held that in reversing the Department's affirmative circumvention finding in the *Final Determination*, the CIT erred in its interpretation of case precedent.[20] The Federal Circuit found that the CIT incorrectly interpreted *Wheatland* to mean that an article cannot be subject to an anti-circumvention inquiry if that article is not expressly included within the literal terms of the order. Specifically, the Federal Circuit reasoned that where *Wheatland* held that a minor alternation inquiry is inappropriate when an order expressly excludes the allegedly altered product, the order at issue contains no explicit exclusion of steel wire rod with a diameter that is less than 5.00 mm.[21] The Federal Circuit also held that substantial evidence supports the Department's determination that small-diameter steel wire rod was not commercially available prior to the *Order*, notwithstanding that some small-diameter steel wire rod was in existence at some prior time in non-investigated countries.[22] Accordingly, the Federal Circuit held that the Department's initial finding in the *Final Determination* that Deacero's entries of wire rod with an actual diameter of 4.75 mm to 5.00 mm constitute a circumventing minor alteration of the *Order* was in accordance with law and supported by substantial evidence.[23]

Timken Notice

In its decision in *Timken*, 893 F.2d at 341, as clarified by *Diamond Sawblades*, the Federal Circuit held that, pursuant to section 516A(e) of the Act, the Department must publish a notice of a court decision that is not "in harmony" with a Department determination and must suspend liquidation of entries pending a "conclusive" court decision. The Federal Circuit's judgement in *Deacero IV* sustaining the Department's original finding in the *Final Determination* that Deacero's entries of wire rod with an actual diameter of 4.75 mm to 5.00 mm constitute a minor alteration circumvention of the *Order* constitutes a final decision of the Court that is not in harmony with the Department's negative circumvention finding in the First Remand Results and *Amended Final Determination*. This notice is published in fulfillment of the publication requirements of *Timken*.

Amended Final Determination

Because there is now a final court decision, we are amending the *Amended Final Determination* with respect to Deacero's entries of wire rod with an actual diameter of 4.75 mm to 5.00 mm. Based on the Federal Circuit's holding in *Deacero IV*, Deacero's entries of wire rod with an actual diameter of 4.75 mm to 5.00 mm are covered by the scope of the *Order* and, thus, subject to AD duties.

Accordingly, the Department will instruct CBP to continue to suspend liquidation of the subject merchandise and, as of January 1, 2015, the effective date for the *Amended Final Determination* giving effect to the CIT's since-reversed final judgment, to set the cash deposit rate for Deacero's entries of wire rod with an actual diameter of 4.75

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[9] *See Final Determination*, 77 FR at 59893.

[10] Petitioners are ArcelorMittal USA LLC, Gerdau Ameristeel U.S. Inc, Rocky Mountain Steel, Members of the Wire Rod Producers Coalition and Nucor Corporation (Nucor).

[11] *See Deacero S.A. de C.V.* v. *United States*, 37 CIT, 942 F. Supp. 2d 1321, 1324–25 (September 20, 2013) (*Deacero I*); *Deacero Remand*, Slip Op. 13–126 at 15.

[12] *See* First Remand Results at 6.

[13] *See Deacero S.A.P.I. de C.V.* v. *United States*, Slip Op. 14–99, 2014 WL 4244349, * 1–3 (August 28, 2014) (*Deacero II*) at 11–12.

[14] *Id.* at 12.

[15] *See* Final Results of Redetermination Pursuant to *Deacero S.A. de C.V. et al.*, v. *United States*, Court No. 12–00345; Slip Op. 14–99 (CIT August 28, 2014) (Second Remand Results).

[16] *See Deacero III*.

[17] *See Amended Final Determination*, 80 FR at 44327.

[18] *Id.*

[19] *Id.*

[20] *See Deacero IV*, 817 F.3d at 1337–39, citing to *Deacero I*, 942 F. Supp. 2d at 1328–1332 quoting *Wheatland Tube Co.* v. *United States*, 161 F.3d 1365, 1370 (Fed. Cir. 1998) (*Wheatland*).

[21] *See Deacero IV*, 817 F.3d at 1338.

[22] *Id.* at 1339.

[23] *Id.* at 1339.

mm to 5.00 mm to the applicable cash deposit rate as determined in administrative reviews.[24] Specifically, for entries of small diameter wire rod from Deacero that entered the United States on or after January 1, 2015, whose entries were suspended at a zero cash deposit rate subject to the *Amended Final Determination,* we will instruct CBP to collect cash deposits at the following rates:

On or after	Before	Applicable cash deposit rate
January 1, 2015	June 22, 2015	[25] 12.08
June 22, 2015	May 19, 2016	[26] 0.00
May 19, 2016		[27] 1.13

Additionally, with regard to any of Deacero's unliquidated entries of wire rod with an actual diameter of 4.75 mm to 5.00 mm for which an administrative review has been completed, we will instruct CBP to assess AD duties at the applicable rates.

Notification to Interested Parties

This notice is issued and published in accordance with sections 516A(e)(1), 751(a)(1), and 777(i)(1) of the Act.

Dated: July 8, 2016.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2016–16803 Filed 7–14–16; 8:45 am]

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DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

Open Meeting of the Commission on Enhancing National Cybersecurity

AGENCY: National Institute of Standards and Technology, Commerce.

ACTION: Notice.

SUMMARY: The Commission on Enhancing National Cybersecurity will meet Tuesday, August 23, 2016, from 9:00 a.m. until 5:00 p.m. Central Time at the University of Minnesota's TCF Bank Stadium-DQ Club Room. The primary purpose of the meeting is to discuss the challenges and opportunities for organizations and consumers in securing the digital economy. In particular, the meeting will address: (1) Challenges confronting consumers in the digital economy; (2) innovation (Internet of Things, healthcare, and other areas); and (3) assured products and services. The meeting will support detailed recommendations to strengthen cybersecurity in both the public and private sectors while protecting privacy, ensuring public safety and economic and national security, fostering discovery and development of new technical solutions, and bolstering partnerships between Federal, State, local, tribal and territorial governments and the private sector in the development, promotion, and use of cybersecurity technologies, policies, and best practices. All sessions will be open to the public.

DATES: The meeting will be held on Tuesday, August 23, 2016, from 9:00 a.m. until 5:00 p.m. Central Time.

ADDRESSES: The meeting will be held at the University of Minnesota's TCF Bank Stadium-DQ Club Room, 3rd Level, located at 420 SE 23rd Avenue, Minneapolis, Minnesota 55455. The meeting is open to the public and interested parties are requested to contact Sara Kerman at the contact information indicated in the **FOR FURTHER INFORMATION CONTACT** section of this notice in advance of the meeting for building entrance requirements.

FOR FURTHER INFORMATION CONTACT: Sara Kerman, Information Technology Laboratory, National Institute of Standards and Technology, 100 Bureau Drive, Stop 2000, Gaithersburg, MD 20899–8900, telephone: 301–975–4634, or by email at: *eo-commission@nist.gov.* Please use subject line "*Open Meeting of the Commission on Enhancing National Cybersecurity—MN*".

SUPPLEMENTARY INFORMATION: Pursuant to the Federal Advisory Committee Act, as amended, 5 U.S.C. App., notice is hereby given that the Commission on Enhancing National Cybersecurity ("the Commission") will meet Tuesday, August 23, 2016, from 9:00 a.m. until 5:00 p.m. Central Time. All sessions will be open to the public. The Commission is authorized by Executive Order 13718, Commission on Enhancing National Cybersecurity.[1] The Commission was established by the President and will make detailed recommendations to strengthen cybersecurity in both the public and private sectors while protecting privacy, ensuring public safety and economic and national security, fostering discovery and development of new technical solutions, and bolstering partnerships between Federal, state, local, tribal and territorial governments and the private sector in the development, promotion, and use of cybersecurity technologies, policies, and best practices.

The agenda is expected to include the following items:

- —Introductions.
- —Panel discussion on the challenges confronting the consumers in the digital economy.
- —Panel discussion on innovation (Internet of Things, healthcare, and other areas).
- —Panel discussion on assured products and services.
- —Conclusion.

Note that agenda items may change without notice. The final agenda will be posted on *http://www.nist.gov/cybercommission.* Seating will be available for the public and media. No registration is required to attend this meeting; however, on-site attendees are asked to voluntarily sign in and space will be available on a first-come, first-served basis.

Public Participation: The Commission agenda will include a period of time, not to exceed fifteen minutes, for oral comments from the public on Tuesday,

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[24] As of January 1, 2015, the cash deposit rate applicable to Deacero's entries of subject merchandise was 12.08 percent, as established in *Carbon and Certain Alloy Steel Wire Rod From Mexico: Final Results of Administrative Review: 2010–2011,* 78 FR 28190, 28191 (May 14, 2013) (*10/11 Final Results*). Deacero's cash deposit rate was subsequently revised to zero percent in *Carbon and Certain Alloy Steel Wire Rod From Mexico: Final Results of Administrative Review: 2012–2013,* 80 FR 35626, 35627 (June 22, 2015) (*12/13 Amended Final Results*), and 1.13 percent in *Carbon and Certain Alloy Steel Wire Rod From Mexico: Amended Final Results of Administrative Review: 2013–2014,* 81 FR 41521, 41522 (June 27, 2016) (*13/14 Amended Final Results.*).

[25] *See 10/11 Final Results,* 78 FR at 28191.

[26] *See 12/13 Amended Final Results,* 80 FR at 35627.

[27] *See 13/14 Amended Final Results,* 81 FR at 41522.

[1] *https://www.federalregister.gov/articles/2016/02/12/2016-03038/commission-on-enhancing-national-cybersecurity.*

August 23, 2016, from 3:00 p.m. until 3:15 p.m. Central Time. Speakers will be selected on a first-come, first-served basis. Each speaker will be limited to five minutes. Questions from the public will not be considered during this period. Members of the public who are interested in speaking are requested to contact Sara Kerman at the contact information indicated in the **FOR FURTHER INFORMATION CONTACT** section of this notice.

Speakers who wish to expand upon their oral statements, those who had wished to speak but could not be accommodated on the agenda, and those who were unable to attend in person are invited to submit written statements. In addition, written statements are invited and may be submitted to the Commission at any time. All written statements should be directed to the Commission Executive Director, Information Technology Laboratory, 100 Bureau Drive, Stop 8900, National Institute of Standards and Technology, Gaithersburg, MD 20899–8900 or by email at: *cybercommission@nist.gov.* Please use subject line "*Open Meeting of the Commission on Enhancing National Cybersecurity—MN*".

Kevin Kimball,

Chief of Staff.

[FR Doc. 2016–16742 Filed 7–14–16; 8:45 am]

BILLING CODE 3510–13–P

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

Flow Cytometry Quantitation Consortium

AGENCY: National Institute of Standards and Technology, Department of Commerce.

ACTION: Notice; request for information.

SUMMARY: The National Institute of Standards and Technology (NIST), an agency of the United States Department of Commerce, is establishing the Flow Cytometry Quantitation Consortium and invites organizations to participate in this Consortium. The Consortium will develop reference materials including reference fluorophore solutions and biological reference materials, reference data and reference methods for assigning equivalent number of reference fluorophores (ERF) values and for assessing the associated uncertainties and utilities. Participation in this Consortium is open to all eligible organizations, as described below.

DATES: NIST will accept responses for participation in this Consortium on an ongoing basis. The Consortium's activities will commence on August 15, 2016 ("Commencement Date"). Acceptance of participants into the Consortium after the Commencement Date will depend on the availability of NIST resources.

ADDRESSES: Information in response to this notice and requests for additional information about the Consortium can be directed via mail to the Consortium Manager, Dr. Lili Wang, Biosystems and Biomaterials Division of NIST's Material Measurement Laboratory, 100 Bureau Drive, Gaithersburg, Maryland 20899–8312, or via electronic mail to *lili.wang@nist.gov.*

FOR FURTHER INFORMATION CONTACT: For further information about partnership opportunities or about the terms and conditions of NIST's Cooperative Research and Development Agreement (CRADA), please contact Honeyeh Zube, CRADA and License Officer, National Institute of Standards and Technology's Technology Partnerships Office, by mail to 100 Bureau Drive, Mail Stop 2200, Gaithersburg, Maryland 20899, by electronic mail to *honeyeh.zube@nist.gov,* or by telephone at (301) 975–2209.

SUPPLEMENTARY INFORMATION: Flow cytometry is a widely used technique for a single cell and particle analysis. It is an essential tool for immunological research, drug and device development, clinical trials, disease diagnosis, and therapy monitoring. The annual expenditure on flow cytometry-related diagnostics is upwards of $1.2 Billion and growing at more than 10 percent per year, testifying to the economic importance of this technology. The measurements made on the different instrument platforms at different times and locations, however, cannot be compared accurately, which makes diagnostic decisions unreliable and slows down advances in biomedical research. In response to this limitation, NIST and International Society for Advancement of Cytometry (ISAC) have developed a methodology to implement quantitation in flow cytometry. The first step is to calibrate the fluorescence signal from microparticles in terms of a unit of equivalent number of reference fluorophores (ERF) on three laser excitations, 405 nm, 488 nm, and 633 nm. The ERF unit gives the number of reference fluorophores in solution which produce the same fluorescence signal as a single dyed microsphere.

The second step uses a biological cell, with known number of specific biomarkers, as a reference material to translate the ERF unit to a unit of antibodies bound per cell (ABC). The ABC unit is most relevant to immunological measurements. To support the calibration of microparticles in terms of ERF, NIST has developed standard reference material (SRM 1934), which includes four solutions of fluorophore: Fluorescein, Nile Red, Coumarin 30 and Allophycocyanin. Microparticles that have been assigned ERF values using SRM 1934 will enable the calibration and characterization of flow cytometers, and the standardization of the fluorescence intensity scale in quantitative ERF units. The results of the collaboration under this Consortium will allow the industry to further research, develop and adopt reference fluorophore solutions for other laser excitations and reference material standards recommended by the expert user community.

NIST is establishing this five-year Consortium to collaborate with manufacturers of microparticles to develop methodologies for assigning ERF values for the microparticles provided to NIST under the scope of the Consortium. The results from this Consortium will also allow NIST to develop the capability that NIST would require to provide a calibration service.

The certificate of analysis for NIST SRM 1934 and NIST's finalized standard operating procedure (SOP) for assigning ERF value will be used for performing the ERF value assignments for participants' microparticles. This SOP includes four steps and is published at J. Res. Natl. Inst. Stand. Technol. 121: 269–286 (2016). As described in the SOP, the ERF value of the major microparticle population is calculated on the basis of the ratio of mean fluorescence intensity values of the major microparticle population to all microparticle populations.

A summary of the ERF value assignments will include ERF values of major microparticle populations, associated combined uncertainties per laser excitation, and reference fluorophore. The combined uncertainty will be derived from all steps of the ERF value assignment, from weighing reference solutions, spectrofluorimeter calibration, CCD response calibration, microparticle concentration measurements by flow cytometer and light obscuration, and measurement of the emission spectrum of microparticles to determine ERF values for major microparticle populations. NIST will also share with each participant any digital emission spectral data of the major microparticle populations. In addition, a participant may request reports for specific ERF value assignments for its microparticles under this Consortium. NIST intends to publish anonymized results of the research under this Consortium. In accordance with 15 U.S.C. 3710a(c)(7)(B), NIST will withhold from public disclosure the data that specifically identifies a participant's microparticles for a period of five (5) years from the date any ERF values are generated, or until the participants grants NIST permission to disclose such data. NIST will not require the participants to pay a membership fee to participate in this Consortium. NIST will, however, require participants to contribute funds to reimburse NIST for the generation of any report requested by a participant for the ERF value assignments of participant's microparticles.

Participation Process: Eligibility will be determined by NIST using the information provided by an organization in response to this notice based on the information requested below.

An organization responding to this notice should provide the following information to NIST's Consortium Manager:

(1) *Type of microparticles:* Optimal sizes of microparticles are from 2 to 10 microns. If there are needs of characterization and ERF value assignment to other size particles (<2 microns or >10 microns), the present standard operating procedure can be modified to accommodate the requests.

(2) *Type of Instrument:* The Consortium is to assign ERF values for microparticles used primarily for flow cytometers. Any information about other instruments used by the organization is helpful to ensure that there is diversity in participants. For example, please indicate if the microparticles are used by the organization with fluorescence microscopes and spectrophotometers/spectrofluorimeters.

(3) Experience in production and characterization of microparticles, antibodies, and biological cells, and analysis of large data sets.

A responding organization should not include any business proprietary information in its response to this request for information. NIST will not treat any information provided in response to this request as proprietary information. NIST will notify each organization of its eligibility. In order to participate in this Consortium, each eligible organization must sign a Cooperative Research and Development Agreement (CRADA) for this Consortium. All participants to this Consortium will be bound by the same terms and conditions.

Kent Rochford,

Associate Director for Laboratory Programs.

[FR Doc. 2016–16761 Filed 7–14–16; 8:45 am]

BILLING CODE 3510–13–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XE733

Gulf of Mexico Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of a public meeting via Webinar.

SUMMARY: The Gulf of Mexico Fishery Management Council will hold a meeting of its Standing and *Reef Fish* Scientific and Statistical Committees (SSC) via Webinar.

DATES: The meeting will be held on Tuesday, August 2, 2016, from 1 p.m. to 3:30 p.m. (EDT), to view the agenda, see **SUPPLEMENTARY INFORMATION.**

ADDRESSES: The meeting will be held via Webinar; you may registering, at *https://attendee.gotowebinar.com/register/3960738127259119362.*

Council address: Gulf of Mexico Fishery Management Council, 2203 N. Lois Avenue, Suite 1100, Tampa, FL 33607; telephone: (813) 348–1630.

FOR FURTHER INFORMATION CONTACT: Steven Atran, Senior Fishery Biologist, Gulf of Mexico Fishery Management Council; *steven.atran@gulfcouncil.org,* telephone: (813) 348–1630.

SUPPLEMENTARY INFORMATION:

Agenda

I. Introductions and adoption of agenda
II. Selection of SSC representative at August, 2016 Council meeting
III. Reevaluation of alternative F_{MSY} proxies (F_{MAX}, $F_{20\%SPR}$, $F_{22\%SPR}$, and $F_{24\%SPR}$) for *red snapper*
IV. Discussion of next *gray triggerfish* assessment—benchmark or standard
V. Review of updated SEDAR schedule
VI. Other business

—Meeting Adjourns—

Please register for SSC Meeting: Standing and *Reef Fish* on Aug. 2, 2016, 1 p.m. (EDT), at *https://attendee.gotowebinar.com/register/3960738127259119362.* After registering, you will receive a confirmation email containing information about joining the Webinar.

The Agenda is subject to change, and the latest version along with other meeting materials will be posted on the Council's file server. To access the file server, the URL is *https://public.gulfcouncil.org:5001/webman/index.cgi,* or go to the Council's Web site and click on the FTP link in the lower left of the Council Web site *http://www.gulfcouncil.org.* The username and password are both "gulfguest." Click on the "Library Folder," then scroll down to "SSC meeting-2016–08."

The meeting will be webcast over the Internet. A link to the webcast will be available on the Council's Web site, *http://www.gulfcouncil.org.*

Although other non-emergency issues not on the agenda may come before the Scientific and Statistical Committee for discussion, in accordance with the Magnuson-Stevens Fishery Conservation and Management Act, those issues may not be the subject of formal action during this meeting. Actions of the Scientific and Statistical Committee will be restricted to those issues specifically identified in the agenda and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the Council's intent to take action to address the emergency.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Kathy Pereira, at the Gulf Council Office (see **ADDRESSES**), at least 5 working days prior to the meeting.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: July 12, 2016.

Tracey L. Thompson,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2016–16745 Filed 7–14–16; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XE723

South Atlantic Fishery Management Council (SAFMC); Public Meetings

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public hearings and scoping meetings.

SUMMARY: The South Atlantic Fishery Management Council (Council) will hold a series of public hearings pertaining to Framework Amendment 4 to the Coastal Migratory Pelagic (CMP) Fishery Management Plan for the Gulf of Mexico and South Atlantic addressing management measures for Atlantic cobia in federal waters, and Amendment 41 to the Snapper Grouper Fishery Management Plan for the South Atlantic addressing measures for mutton snapper in federal waters. Scoping comments will also be accepted for options being considered in Joint Dolphin Wahoo Amendment 10 and Snapper Grouper Amendment 44 to address allocations for dolphin fish and yellowtail snapper in federal waters. Question and Answer sessions for Framework Amendment 4 to the CMP Fishery Management Plan and for Amendment 41 to the Snapper Grouper Fishery Management Plan will also be held via webinar. A Question and Answer session for Joint Dolphin Wahoo Amendment 10 and Snapper Grouper Amendment 44 will be held as part of the scoping session.

DATES: The Q&A sessions and series of public hearings/scoping meetings will be held from August 1 through August 17, 2016. All webinars and meetings will begin at 6 p.m.

Registration is required for the Q&A sessions and public hearing/scoping meetings held via webinar. Registration information will be posted on the SAFMC Web site at *www.safmc.net* as it becomes available.

ADDRESSES: *Council address:* South Atlantic Fishery Management Council, 4055 Faber Place Drive, Suite 201, N. Charleston, SC 29405. For additional information on the Webinars, Hearings, and Agenda, see Dates, Addresses, and Agenda.

FOR FURTHER INFORMATION CONTACT: Kim Iverson, Public Information Officer, SAFMC; phone: (843) 571–4366 or toll free (866) SAFMC–10; fax: (843) 769–4520; email: *kim.iverson@safmc.net.*

SUPPLEMENTARY INFORMATION: The Council is soliciting public hearing comments on proposed measures in CMP Framework Amendment 4 addressing proposed management measures for Atlantic cobia in federal waters from the Florida/Georgia line northward to New York. The Atlantic cobia fishery was closed to recreational harvest on June 20, 2016 in federal waters after NOAA Fisheries determined that the recreational annual catch limit had been exceeded in 2015. Exceeding the 2015 annual catch limit triggered the accountability measures in place for Atlantic cobia to prevent overfishing, resulting in the shortened recreational season in 2016. Measures proposed in Framework Amendment 4 are designed to help ensure consistent and stable fishing opportunities for all participants in the fishery and include: (1) Reducing the recreational bag limit with a preferred alternative to reduce the daily bag limit from 2 per person/day to 1 per person/day; (2) establishing a recreational vessel limit with a preferred alternative of 3 per vessel/day; (3) modifying the recreational fishing year with a preferred alternative for the year to begin May 1st; (4) modifying the recreational minimum size limit; (5) modifying the current accountability measure; and (6) changes to the commercial harvest limit.

The Council is also soliciting public hearing comments on Snapper Grouper Amendment 41 addressing proposed management measures for mutton snapper. Stakeholders have expressed concerns about fishing pressure that occurs each spring as mutton snapper gather to spawn. Measures in Amendment 41 include actions to: (1) Modify the current annual catch limit for mutton snapper based on the most recent stock assessment; (2) reduce the current bag limit of 10 fish per person/day within the snapper aggregate with a preferred alternative of 3 fish per person/day year round; (3) establish a commercial trip limit with the preferred alternative of 300 pounds and 3 fish per person/day during the spawning season months (April-June); and (4) modify the current minimum size limit with the preferred alternative to increase the limit from 16 to 18 inches total length.

Public scoping comments are being solicited for measures proposed in Joint Dolphin Wahoo Amendment 10/Snapper Grouper Amendment 44 addressing potential allocation measures for dolphin fish and yellowtail snapper. Public scoping occurs early in the amendment development process and the Council is soliciting input on proposed options that include a common pool allocation, a reserve category, temporary shifts in allocation, combined annual catch limits, a permanent allocation shift for dolphin and/or yellowtail snapper, and allocations by gear type for the commercial sector in the dolphin fishery. Measures proposed for dolphin would apply in federal waters along the entire Atlantic coast.

Dates, Addresses, and Agenda

Webinars

1. August 1, 2016—Q&A Session and Public Hearing for CMP Framework Amendment 4 (Atlantic Cobia)
2. August 2, 2016—Q&A Session and Public Hearing for Snapper Grouper Amendment 41 (Mutton Snapper)
3. August 4, 2016—Q&A Session and Public Scoping of Joint Dolphin Wahoo Amendment 10/Snapper Grouper Amendment 44 (Allocation of Dolphin and Yellowtail Snapper)

In-Person Public Hearings

Coastal Migratory Pelagics Framework Amendment 4 (Atlantic Cobia)

1. August 3, 2016—Crowne Plaza Hotel, 4831 Tanger Outlet Boulevard, N. Charleston, SC 29418; phone: (843) 744–4422.
2. August 8, 2016—Holton Restaurant, 13711 E. Oglethorpe Highway, Midway, GA 31320; phone: (912) 884–9151.
3. August 9, 2016—Hilton Virginia Beach, 3001 Atlantic Avenue, Virginia Beach, VA 23451; phone: (757) 213–3001.
4. August 9, 2016—Hampton Inn, 29 William Pope Drive, Bluffton, SC 29909; phone: (843) 705–9000.
5. August 10, 2016—NC Division of Marine Fisheries, Central District Office, 5285 Highway 70 West, Morehead City, NC 28557; phone: (252) 499–9200.
6. August 11, 2016—Hilton Garden Inn, 5353 N. Virginia Dare Trail, Kitty Hawk, NC 27949; phone: (252) 261–1290.
7. August 11, 2016—Murrells Inlet Community Center, 4462 Murrells Inlet Road, Murrells Inlet, SC 29576; phone: (904) 396–5100.

Snapper Grouper Amendment 41 (Mutton Snapper)

1. August 15, 2016—Hilton Garden Inn—Ft. Lauderdale Airport, 180 SW 18th Avenue, Dania Beach, FL 33004; phone: (954) 924–9204.
2. August 16, 2016—Hawks Cay Resort, 61 Hawks Cay Blvd., Duck Key, FL 33050; phone: (305) 743–7000.
3. August 17, 2016—Marriott Beachside Hotel, 3841 N. Roosevelt Blvd., Key West, FL 33040; phone: (305) 296–8100.

Submitting Written Comments

The Council requests that written comments be submitted using the online public comment form. Comments submitted using the online comment form are immediately posted to the Council's Web site at *www.safmc.net* and available for all Council members and the public to view. Written comments may also be submitted by mail or fax.

The comment period will open on July 18, 2016 once amendment materials are posted to the Web site. All written comments are due by 5 p.m. on August 19, 2016.

Comments may be submitted by mail to: Gregg Waugh, Executive Director, SAFMC, 4055 Faber Place Drive, Suite 201, North Charleston, SC 29405. Fax comments to (843) 769–4520. Comments using the online public comment form: Use the comment form links on the Public Hearing and Scoping Meeting page on the Council's Web site to submit comments on each amendment. All comments submitted will be automatically posted to the Web site and accessible for the public to view. The direct link to the Public Hearing and Scoping meeting page is: *http://safmc.net/meetings/public-hearing-and-scoping-meeting-schedule.*

Copies of the public hearing documents, scoping document, and other relevant informational material will be posted on the Council's Web site at *www.safmc.net* as they become available.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for auxiliary aids should be directed to the council office (see **ADDRESSES**) 3 days prior to the meeting.

Note: The times and sequence specified in this agenda are subject to change.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: July 12, 2016.

Jeffrey N. Lonergan,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2016–16801 Filed 7–14–16; 8:45 am]

BILLING CODE 2510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XE734

Mid-Atlantic Fishery Management Council (MAFMC); Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; public meeting.

SUMMARY: The Mid-Atlantic Fishery Management Council's (Council's) Summer Flounder, Scup, and Black Sea Bass Advisory Panel will hold a public meeting, jointly with the Atlantic States Marine Fisheries Commission's (ASMFC) Summer Flounder, Scup, and Black Sea Bass Advisory Panel.

DATES: The meeting will be held on Friday, July 29, 2016, from 10 a.m. until 12:30 p.m.

ADDRESSES: The meeting will be held via webinar with a telephone-only connection option. Details on webinar registration and telephone-only connection details will be posted at: *http://www.mafmc.org.*

Council address: Mid-Atlantic Fishery Management Council, 800 N. State Street, Suite 201, Dover, DE 19901; telephone: (302) 674–2331 or on their Web site at *www.mafmc.org.*

FOR FURTHER INFORMATION CONTACT: Christopher M. Moore, Ph.D., Executive Director, Mid-Atlantic Fishery Management Council, telephone: (302) 526–5255.

SUPPLEMENTARY INFORMATION: The purpose of this meeting is for the Advisory Panels to review and comment on recent stock assessment information, as well as the reports and recommendations of the Council's Scientific and Statistical Committee (SSC) and the Summer Flounder, Scup, and Black Sea Bass Monitoring Committee regarding previously implemented fishery specifications (*i.e.*, catch and landings limits and management measures) for 2017–18. The Council and ASMFC will consider input from the AP in August when reviewing these specifications.

Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aid should be directed to M. Jan Saunders, (302) 526–5251, at least 5 days prior to the meeting date.

Dated: July 12, 2016.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2016–16766 Filed 7–14–16; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Telecommunications and Information Administration

Commerce Spectrum Management Advisory Committee Meeting

AGENCY: National Telecommunications and Information Administration, U.S. Department of Commerce.

ACTION: Notice of open meeting.

SUMMARY: This notice announces a public meeting of the Commerce Spectrum Management Advisory Committee (Committee). The Committee provides advice to the Assistant Secretary of Commerce for Communications and Information and the National Telecommunications and Information Administration (NTIA) on spectrum management policy matters.

DATES: The meeting will be held on August 1, 2016, from 1:00 p.m. to 4:00 p.m., Mountain Daylight Time (MDT).

ADDRESSES: The meeting will be held at the National Institute of Standards and Technology, Boulder Campus, 325 Broadway Street, Boulder, CO 80305. Additional information regarding the location and registration for attendance at this meeting is included in the **SUPPLEMENTARY INFORMATION** section, below. Public comments may be mailed to Commerce Spectrum Management Advisory Committee, National Telecommunications and Information Administration, 1401 Constitution Avenue NW., Room 4600, Washington, DC 20230 or emailed to *dreed@ntia.doc.gov.*

FOR FURTHER INFORMATION CONTACT: David J. Reed, Designated Federal Officer, at (202) 482–5955 or *dreed@ntia.doc.gov;* and/or visit NTIA's Web site at *http://www.ntia.doc.gov/category/csmac.*

SUPPLEMENTARY INFORMATION:

Background: The Committee provides advice to the Assistant Secretary of Commerce for Communications and Information on needed reforms to domestic spectrum policies and management in order to: License radio frequencies in a way that maximizes public benefits; keep wireless networks as open to innovation as possible; and make wireless services available to all Americans. *See* Charter at *http://www.ntia.doc.gov/files/ntia/publications/csmac_2015_charter_renewal_2-26-15.pdf.*

This Committee is subject to the Federal Advisory Committee Act (FACA), 5 U.S.C. App. 2, and is consistent with the National Telecommunications and Information Administration Act, 47 U.S.C. 904(b). The Committee functions solely as an advisory body in compliance with the FACA. For more information about the Committee visit: *http://www.ntia.doc.gov/category/csmac.*

Matters to Be Considered: The Committee provides advice to the Assistant Secretary to assist in developing and maintaining spectrum management policies that enable the United States to maintain or strengthen its global leadership role in the introduction of communications technology, services, and innovation;

thus expanding the economy, adding jobs, and increasing international trade, while at the same time providing for the expansion of existing technologies and supporting the country's homeland security, national defense, and other critical needs of government missions. The Committee will hear reports of the following Subcommittees:

1. Federal Access to Non-Federal Bands (Bi-directional Sharing)
2. Agency and Industry Collaboration
3. Measurement and Sensing in the 5 GHz Band
4. Spectrum Access System (SAS)/ Spectrum Database International Extension
5. Fifth Generation (5G) Wireless

NTIA will post a detailed agenda on its Web site, *http://www.ntia.doc.gov/category/csmac,* prior to the meeting. To the extent that the meeting time and agenda permit, any member of the public may speak to or otherwise address the Committee regarding the agenda items. *See Open Meeting and Public Participation Policy,* available at *http://www.ntia.doc.gov/category/csmac.*

Time and Date: The meeting will be held on August 1, 2016, from 1:00 p.m. to 4:00 p.m. MDT. The meeting time and the agenda topics are subject to change. The meeting will be available via two-way audio link and may be webcast. Please refer to NTIA's Web site, *http://www.ntia.doc.gov/category/csmac,* for the most up-to-date meeting agenda and access information.

Place: The meeting will be held at the National Institute of Standards and Technology, Boulder Campus, 325 Broadway Street, Boulder, CO 80305. The specific location is PML Building 81, Conference Room A116. All attendees, including both committee members and meeting observers, must pre-register in order to gain entry to the NIST campus. To register, please visit: *https://appam.certain.com/profile/form/index.cfm?PKformID=0x310288cc0.* Security and campus instructions will be sent via email to registered attendees prior to the meeting date. Valid photo identification must be presented at the main gate. All foreign national visitors who do not have permanent resident status and who wish to register for the meeting will be required to provide additional information in order to complete registration. For directions to NIST, please visit: *http://www.nist.gov/public_affairs/visitor/boulder-visitor-info.cfm.*

The meeting will be open to the public and members of the press on a first-come, first-served basis as space is limited. The public meeting is physically accessible to people with disabilities. Individuals requiring accommodations, such as sign language interpretation or other ancillary aids, are asked to notify Mr. Reed at (202) 482–5955 or *dreed@ntia.doc.gov* at least ten (10) business days before the meeting.

Status: Interested parties are invited to attend and to submit written comments to the Committee at any time before or after the meeting. Parties wishing to submit written comments for consideration by the Committee in advance of a meeting may send them via postal mail to Commerce Spectrum Management Advisory Committee, National Telecommunications and Information Administration, 1401 Constitution Avenue NW., Room 4600, Washington, DC 20230. It would be helpful if paper submissions also include a compact disc (CD) that contains the comments in Microsoft Word and/or PDF file formats. CDs should be labeled with the name and organizational affiliation of the filer. Alternatively, comments may be submitted via electronic mail to *dreed@ntia.doc.gov* and should also be in one or both of the file formats specified above. Comments must be received five (5) business days before the scheduled meeting date in order to provide sufficient time for review. Comments received after this date will be distributed to the Committee, but may not be reviewed prior to the meeting.

Records: NTIA maintains records of all Committee proceedings. Committee records are available for public inspection at NTIA's Washington, DC office at the address above. Documents including the Committee's charter, member list, agendas, minutes, and reports are available on NTIA's Web site at *http://www.ntia.doc.gov/category/csmac.*

Dated: July 12, 2016.

Kathy D. Smith,

Chief Counsel, National Telecommunications and Information Administration.

[FR Doc. 2016–16757 Filed 7–14–16; 8:45 am]

BILLING CODE 3510–60–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Electronic Filing of Certain Import/Export Data Relating to Controlled Substances and Listed Chemicals: Announcement of the Partner Government Agency Message Set/Document Image System Test and Request for Participants

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: General notice.

SUMMARY: The Drug Enforcement Administration (DEA) announces, in coordination with U.S. Customs and Border Protection (CBP), a pilot test of the International Trade Data System (ITDS) involving the electronic submission of data related to the importation and exportation of controlled substances and listed chemicals. The pilot program will test the electronic transmission through the CBP's Automated Commercial Environment (ACE) system, of data, forms and documents required by the DEA using the Partner Government Agency (PGA) Message Set and the Document Image System (DIS). The data, forms and documents will be transmitted for review by the DEA. CBP's PGA Message Set and DIS enable importers, exporters, and brokers to electronically transmit data required by the DEA directly to ACE. This electronic process will replace certain paper-based processes currently used during the pilot program for pilot participants.

DATES: The test will commence no earlier than August 1, 2016, and will continue until concluded by publication of a notice in the **Federal Register** ending the test. Applications to participate may be submitted throughout the duration of this test.

FOR FURTHER INFORMATION CONTACT: For PGA-related questions, contact Elizabeth McQueen at *elizabeth.mcqueen@cbp.dhs.gov.* For technical questions related to the ACE or Automated Broker Interface (ABI) transmissions, or the PGA message set/DIS data transmission, contact your assigned client representative. Interested parties without an assigned client representative should direct their questions to Steven Zaccaro at *steven.j.zaccaro@cbp.dhs.gov* with the subject heading "*DEA Message Set/DIS Test FRN-Request to Participate.*" For DEA-related questions, contact Cathy A. Gallagher, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (202) 598–6812.

To Apply: Any party seeking to participate in this test should contact their CBP client representative. Interested parties without an assigned client representative should send a request to Steven Zaccaro at *steven.j.zaccaro@cbp.dhs.gov* with the subject heading "*DEA Message Set/DIS Test FRN-Request to Participate.*" Applications will be accepted throughout the duration of this test. Applicants should identify the DEA-regulated commodities they intend to import or export and the ports they intend to use to import or export those commodities. Applicants will be notified by CBP/client representatives of the date they may begin participating in this test. Any applicant who provides incomplete information or otherwise does not meet participation requirements will be notified by email and given an opportunity to resubmit a request to participate. To be eligible to apply for and participate in the pilot, an applicant must be a self-filing importer or broker who has the ability to file ACE Entry and Entry Summaries certified for cargo release using a software program that has completed ACE certification testing for the PGA Message Set and DIS, and, if an exporter, must have the ability to file electronically in the Automated Export System (AES) or in ACE AESDirect.

SUPPLEMENTARY INFORMATION:

Background

The Customs Modernization provisions in the North American Free Trade Agreement Implementation Act (Pub. L. 103–183, 107 Stat. 2057, 2170, December 8, 1993) provide the Commissioner of CBP with authority to conduct limited test programs or procedures designed to evaluate planned components of the National Customs Automation Program (NCAP), which includes ACE. The PGA Message Set/DIS test described in this notice is in furtherance of the NCAP goals.

This test is also in furtherance of the International Trade Data System (ITDS) key initiatives to achieve the vision of ACE as the "single window" for the U.S. Government and trade community, set forth in section 405 of the Security and Accountability for Every Port Act of 2006 ("SAFE Port Act") (Pub. L. 109–347, 120 Stat. 1884, 1929, Oct. 13, 2006), and section 107 of the Trade Facilitation and Trade Enforcement Act of 2015 (Pub. L. 114–125, 130 Stat. 122, 135, Feb. 24, 2016). The purpose of ITDS, as stated in section 405 of the SAFE Port Act, is to eliminate redundant information requirements, efficiently regulate the flow of commerce, and effectively enforce laws and regulations relating to international trade, by establishing a single portal system, operated by CBP, for the collection and distribution of standard electronic import and export data required by all participating Federal agencies. CBP is developing ACE as the "single window" for the trade community to transmit electronically all required information related to the cargo imported or exported and to comply with the ITDS requirement established by the SAFE Port Act. On October 13, 2015, CBP promulgated an interim final rule providing that, as of November 1, 2015, ACE is a CBP authorized Electronic Data Interchange (EDI) system which may be used for the filing of entries and entry summaries. 80 FR 61278. On February 29, 2016, CBP published a notice in the **Federal Register** stating that effective March 31, 2016, electronic entry summaries for specified entry types must be filed in ACE, and that effective May 28, 2016, electronic entries for specified entry types must be filed in ACE. 81 FR 10264.

Executive Order 13659 of February 19, 2014, *Streamlining the Export/Import Process for America's Businesses,* 79 FR 10655 (Feb. 25, 2014), requires that by December 31, 2016, the ITDS "single window," have the operational capabilities to serve as the primary means of receiving from users the standard set of data and other relevant documentation (exclusive of applications for permits, licenses, or certifications) required for the release of imported cargo and clearance of cargo for export, and to transition from paper-based requirements and procedures to faster and more cost-effective electronic submissions to, and communications with, participating U.S. Government agencies.

Partner Government Agency Message and Document Image System

On December 13, 2013, CBP published in the **Federal Register** a notice announcing an NCAP test called the Partner Government Agency (PGA) Message Set test. 78 FR 75931. The PGA Message Set is the data needed to satisfy the PGA reporting requirements. ACE enables the message set by acting as the "single window" for the electronic transmission to CBP of trade-related data required by the PGAs. Once validated, the data will be made available to the relevant PGAs involved in regulating the importation or exportation of the cargo import, export, and transportation-related decision making. The data will be used to fulfill cargo entry requirements and may allow for earlier release decisions and more certainty for the importer in determining the logistics of cargo delivery. Also, by virtue of being electronic, the PGA Message Set will eliminate the necessity for the submission and subsequent handling of most paper documents.

On April 6, 2012, CBP announced the DIS test (77 FR 20835) allowing any party who files an ACE entry/cargo release or ACE Entry Summary certified for cargo release to submit electronically digital copies of specified CBP and PGA forms and documents via a CBP-approved EDI. On January 30, 2015, CBP modified the DIS test to allow specified Animal and Plant Health Inspection Service forms and documents to be transmitted as attachments to an email. 80 FR 5126. On October 15, 2015, CBP announced it would permit any DIS eligible form or document to be submitted as an attachment to an email. 80 FR 62082. As CBP frequently updates the list of forms and documents eligible to be transmitted using DIS, the complete list will be maintained on the CBP Web site, at the following address: *http://www.cbp.gov/trade/ace/features* under the DIS tab. Only eligible documents and forms required for the release of cargo or requested by CBP should be transmitted using DIS. Forms and documents transmitted using DIS may be transmitted without a prior request from CBP or the relevant PGA. ACE will automatically acknowledge every successful DIS transmission. This automated acknowledgement of successful transmission does not mean the correct or required form or document was transmitted as it occurs prior to any review of the transmitted form or document. Any DEA form or document submitted via DIS is an electronic copy of an original document or form, and both the original and the imaged copy are subject to the CBP recordkeeping requirements of 19 CFR part 163, DEA recordkeeping requirements found in 21 CFR parts 1304, 1310, 1312 and 1313, and any other applicable PGA recordkeeping requirements. For purposes of the pilot, every form or document transmitted through DIS must be legible and must be a complete, accurate, and unaltered copy of the original document. *See* 19 CFR 101.9(b). For more information and the rules, procedures, technical requirements and terms and conditions applicable to the DIS, please see the DIS **Federal Register** notice at 80 FR 62082 (Oct. 15, 2015).

Current Paper Based Procedure

Current DEA regulations require applications for permits, declarations, and other required notices and reports to be filed utilizing designated forms which can be filed in paper form or by electronic means. During the pilot, the DEA import and export application and filing processes will continue to remain separate from (and in advance of) the ITDS single window. Entities will continue to use the DEA application and filing processes; however, the processes will be electronic rather than paper. After the DEA's approval or notification of receipt as appropriate, the DEA will transmit the necessary information electronically to the ITDS and the registrant or regulated person.

In support of ITDS and the use of CBP's PGA Message Set and DIS, the DEA will utilize an automated system to ensure compliance with import and export regulations. The DEA's system will electronically transmit reference data to CBP, expediting the conditional release of shipments for the purpose of inspection, prior to the final release into the commerce of the United States.

PGA Message Set/ACE Filing

Once deployed, ACE/ITDS will replace the Automated Commercial System (ACS), the current EDI. ACE will be the official "single-window" system of record. ACE will require that all data related to cargo release be submitted electronically using either the PGA Message Set or DIS.

The DEA and/or CBP will analyze the PGA Message Set data, forms and documents transmitted using DIS to determine whether inspection of a shipment is required. The data in ACE will also enable CBP to make the determination that a shipment may be conditionally released for inspection.

Pilot Program Details

The DEA is authorized by the Controlled Substances Act (CSA) (21 U.S.C. 801 *et seq.*), as amended, to regulate and collect information on the importation and exportation of controlled substances and listed chemicals. Under applicable DEA regulations, the importation of these DEA-regulated commodities into the customs territory of the United States from any place outside thereof (but within the United States), or into the United States from any place outside thereof, or the exportation of these DEA-regulated commodities from the United States typically requires the submission of one or more of the following DEA forms:

(1) DEA Form 35—Permit to Import
(2) DEA Form 36—Permit to Export
(3) DEA Form 161—Application for Permit to Export Controlled Substances
(4) DEA Form 161R—Application for Permit to Export Controlled Substances for Subsequent Reexport
(5) DEA Form 236—Controlled Substances Import/Export Declaration
(6) DEA Form 357—Application for Permit To Import Controlled Substances
(7) DEA Form 486—Import/Export Declaration for List I and List II Chemicals;
(8) DEA Form 486A—Import Declaration for Ephedrine, Pseudoephedrine, or Phenylpropanolamine.

This notice announces DEA's plan to conduct a test concerning the electronic transmission of the data contained in these forms to ACE using the PGA Message Set and the transmission of certain DEA permits, forms and documents using DIS. This new DEA PGA Message Set and DIS capability will satisfy the DEA data and electronic document requirements for any CBP entry filed electronically in ACE. As noted above, this test also applies to the exportation of the commodities subject to this test and requires the electronic submission of required export data through AES in Automated Export System Trade Interface Requirements (AESTIR) or American National Standards Institute (ANSI) X12, or in ACE AESDirect using an ACE portal, bulk upload or weblink. The AES DEA data elements are documented in Appendix Q of the AESTIR Implementation Guidelines (Appendix Q) and in the ACE AESDirect portal view. The Web site to Appendix Q is *http://www.cbp.gov/document/guidance/aestir-draft-appendix-q-pga-record-formats.*

This new capability will also enable the trade community to have a CBP-managed "single window" for the electronic submission of data and documents required by the DEA during the cargo importation/exportation and review process. The technical requirements for submitting DEA data elements are set forth in the supplemental Customs and Trade Automated Interface Requirements (CATAIR) guidelines for the DEA. These technical requirements, including the ACE CATAIR chapter, may be found at the following link: *http://www.cbp.gov/trade/ace/catair.*

The list of forms and documents, including DEA documents, which may be transmitted using DIS may be found at *http://www.cbp.gov/trade/ace/features* under the DIS tab. The DEA permits, forms and documents eligible to be transmitted using DIS include DEA forms 35, 36, 236, 486 and 486A.

This test will apply to any entry filed in ACE at any port of entry and to cargo imported or exported using any mode of transportation. As a condition of the pilot, entries filed in ACE with the PGA Message Set must be transmitted using a software program that has completed ACE certification testing. *See* 19 CFR 101.9(b). This test will apply to all cargo regulated by DEA as of the date of this notice that require a CBP entry or exit.

This initial pilot will include the DEA PGA Message Set and the DIS components of ACE for imports, and the use of AES for exports. As mentioned above, DIS allows participants to transmit required PGA data to ACE through the use of electronic copies of DEA permits, forms and documents. For information regarding the use of DIS and a list of PGA forms and documents that may be transmitted to ACE using DIS, please see *http://www.cbp.gov/trade/ace/features under the DIS tab.*

Importers, exporters and brokers who participate in this pilot will transmit PGA Message Set data to ACE using the electronic data interchange known as the ABI, and for exports, data will be transmitted via the AESTIR or the ACE Secure Data Portal. The data elements in the PGA Message Set are generally those found on the DEA forms, permits, and declarations subject to this test. The DEA data is required in order to determine whether inspection of the shipment is required and to provide CBP with information to determine whether to conditionally release the cargo. Details related to this data will be provided to pilot participants. The DEA anticipates that this pilot program will help prepare for a successful transition from the paper-based process to the electronic entry and transmission of data to ACE.

Pilot Program Participant Responsibilities

Importers, exporters and brokers who participate in this PGA Message Set/DIS pilot will be required to:

- Submit by electronic means through the DEA Office of Diversion Control's secure network application, DEA Registered Importers/Exporters Permit Applications (DEA Forms 357, 161, 161R), and Import/Export Declarations (DEA Forms 236, 486, and 486A).
- Retrieve and print from the DEA Office of Diversion Control's secure network application, color copies of DEA issued import and export permits (DEA Forms 35 and 36).
- Obtain the required PGA Message Set Data and electronic DIS copy of the permit or declaration from the DEA registrant or regulated person.
- File, when applicable, data elements contained in Appendix Q.
- Include PGA Message Set import filings only as part of an ACE Entry or Entry Summary certified for cargo release.
- Use a software program that has completed ACE certification testing for the PGA Message Set and/or DIS.
- Transmit import filings to CBP via ACE.
- Transmit only information to CBP that has been requested by CBP or DEA.

- File export data through AES in AESTIR or ANSI X12, or in ACE AESDirect using an ACE portal, bulk upload or weblink.

Waiver of Regulations Under the Test

Pursuant to the authority of 21 U.S.C. 871(b), for the purposes of this test, the DEA waives for pilot participants those provisions of 21 CFR parts 1312 and 1313 that are inconsistent with the terms of this test. This document does not waive any recordkeeping requirements found in 21 CFR parts 1304, 1310, 1312, and 1313. For purposes of this test, those provisions of 21 CFR 1312.13(e), 1312.14(a), 1312.14(c), 1312.19(a), 1312.19(b), 1312.23(e), 1312.24(a), 1312.24(b), 1312.28(c), 1312.28(d), 1313.14(c), and 1313.23(c) that are inconsistent with the terms of this test are waived for test participants.

Paperwork Reduction Act

This change does not institute a new collection of information but instead proposes modifying the way that information is gathered. The collection of information contained in this DEA PGA Message Set/DIS test has been previously approved by the Office of Management and Budget (OMB) in accordance with the requirements of the Paperwork Reduction Act (44 U.S.C. 3507) and assigned OMB control numbers 1117–0009 and 1117–0023. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number assigned by OMB.

Confidentiality

Data submitted and entered into the ACE Portal includes information that is exempt or restricted from disclosure by law, such as by the Trade Secrets Act (18 U.S.C. 1905). Participation in this or any of the previous ACE tests is not confidential and the name(s) of an approved participant(s) may be disclosed by CBP.

Dated: July 8, 2016.

Louis J. Milione,

Deputy Assistant Administrator.

[FR Doc. 2016–16756 Filed 7–14–16; 8:45 am]

BILLING CODE 4410–09–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List: Proposed Additions and Deletions

AGENCY: Committee for Purchase From People Who are Blind or Severely Disabled.

ACTION: Proposed additions to and deletions from the Procurement List.

SUMMARY: The Committee is proposing to add a product and service to the Procurement List that will be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities, and delete products and services previously furnished by such agencies.

DATES: Comments must be received on or before: 8/14/2016.

ADDRESSES: Committee for Purchase From People Who Are Blind Or Severely Disabled, 1401 S. Clark Street, Suite 715, Arlington, Virginia 22202–4149.

FOR FURTHER INFORMATION CONTACT: For further information or to submit comments contact Barry S. Lineback, Telephone: (703) 603–7740, Fax: (703) 603–0655, or email *CMTEFedReg@AbilityOne.gov.*

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C. 8503(a)(2) and 41 CFR 51–2.3. Its purpose is to provide interested persons an opportunity to submit comments on the proposed actions.

Additions

If the Committee approves the proposed additions, the entities of the Federal Government identified in this notice will be required to procure the product and service listed below from nonprofit agencies employing persons who are blind or have other severe disabilities.

The following product and service are proposed for addition to the Procurement List for production by the nonprofit agencies listed:

Product:

NSN(s)—Product Name(s): MR 343—Handheld Spiralizer
Mandatory for: Military commissaries and exchanges in accordance with the Code of Federal Regulations, Chapter 51, 51–6.4
Mandatory Source(s) of Supply: Cincinnati Association for the Blind, Cincinnati, OH
Contracting Activity: Defense Commissary Agency
Distribution: C-List

Service:

Service Type: Facilities Maintenance Service
Mandatory for: U.S. Army, DPW, Fort Riley (excluding Residential Housing Areas and including Forbes Air Field, Topeka, KS), Fort Riley, KS
Mandatory Source(s) of Supply: Training, Rehabilitation, and Development Institute, Inc., San Antonio, TX
Contracting Activity: U.S. Army Corps of Engineers, Support Center, Huntsville, AL
Service Type: Administrative Support Service
Mandatory for: FAA, Regional Offices (except Burlington, MA) Fort Worth, TX
Mandatory Source of Supply: ServiceSource, Inc., Oakton, VA
Contracting Activity: Department of Transportation, Federal Aviation Administration Southwest Region, Logistics Division (ASW–55), Fort Worth, TX

Deletions

The following products and services are proposed for deletion from the Procurement List:

Products:

NSN(s)—Product Name(s):

8410–01–279–7730—Skirt, Gabardine, Lined, Marine Corps, Women's, Blue, 6 Short
8410–01–279–7731—Skirt, Gabardine, Lined, Marine Corps, Women's, Blue, 6R
8410–01–279–7732—Skirt, Gabardine, Lined, Marine Corps, Women's, Blue, 6L
8410–01–279–7733—Skirt, Gabardine, Lined, Marine Corps, Women's, Blue, 8S
8410–01–279–7734—Skirt, Gabardine, Lined, Marine Corps, Women's, Blue, 8R
8410–01–279–7735—Skirt, Gabardine, Lined, Marine Corps, Women's, Blue, 8L
8410–01–279–7736—Skirt, Gabardine, Lined, Marine Corps, Women's, Blue, 10S
8410–01–279–7737—Skirt, Gabardine, Lined, Marine Corps, Women's, Blue, 10R
8410–01–279–7738—Skirt, Gabardine, Lined, Marine Corps, Women's, Blue, 10L
8410–01–279–7739—Skirt, Gabardine, Lined, Marine Corps, Women's, Blue, 12S
8410–01–279–7740—Skirt, Gabardine, Lined, Marine Corps, Women's, Blue, 12R
8410–01–279–7741—Skirt, Gabardine, Lined, Marine Corps, Women's, Blue, 12L
8410–01–279–7742—Skirt, Gabardine, Lined, Marine Corps, Women's, Blue, 14S
8410–01–279–7743—Skirt, Gabardine, Lined, Marine Corps, Women's, Blue, 14R
8410–01–279–7744—Skirt, Gabardine, Lined, Marine Corps, Women's, Blue, 14L
8410–01–279–7745—Skirt, Gabardine, Lined, Marine Corps, Women's, Blue, 16S
8410–01–279–7746—Skirt, Gabardine, Lined, Marine Corps, Women's, Blue, 16R

8410–01–279–7747—Skirt, Gabardine, Lined, Marine Corps, Women's, Blue, 16L
8410–01–279–7748—Skirt, Gabardine, Lined, Marine Corps, Women's, Blue, 18S
8410–01–279–7749—Skirt, Gabardine, Lined, Marine Corps, Women's, Blue, 18R
8410–01–279–7750—Skirt, Gabardine, Lined, Marine Corps, Women's, Blue, 18L
8410–01–279–7751—Skirt, Gabardine, Lined, Marine Corps, Women's, Blue, 20S
8410–01–279–7752—Skirt, Gabardine, Lined, Marine Corps, Women's, Blue, 20R
8410–01–279–7753—Skirt, Gabardine, Lined, Marine Corps, Women's, Blue, 20L

Contracting Activity: Defense Logistics Agency Troop Support

NSN(s)—Product Name(s):

7520–01–385–7362—Pencil, Mechanical, Side Action, Green Barrel, 0.7 mm
7520–01–354–2305—Pencil, Mechanical, Push Action, Red Barrel and Lead, Extra Bold Point (1.1 mm)

Mandatory Source(s) of Supply: San Antonio Lighthouse for the Blind, San Antonio, TX

Contracting Activity: General Services Administration, New York, NY

NSN(s)—Product Name(s):

7510–01–443–2121—Toner, Cartridges, New
7510–00–NIB–0633—Skilcraft Toner Cartridge
7510–00–NIB–0642—Skilcraft Toner Cartridge

Mandatory Source(s) of Supply: Alabama Industries for the Blind, Talladega, AL

Contracting Activity: General Services Administration, New York, NY

NSN(s)—Product Name(s):

7045–01–599–5322—Glare Shield for iPhone
7045–01–599–5271—Glare Shield for Blackberry Bold
7045–01–599–5273—Glare Shield for Blackberry Storm2
7045–01–599–5290—Glare Shield for Blackberry Curve2
7045–01–599–5275—Universal PDA Glare Shield
7045–01–599–5287—Privacy Shield for iPhone
7045–01–599–5276—Privacy Shield for Blackberry Bold
7045–01–599–5278—Privacy Shield for Blackberry Storm2
7045–01–599–5285—Privacy Shield for Blackberry Curve2
7045–01–599–5282—Privacy Shield for PDA, Universal

Mandatory Source(s) of Supply: Wiscraft, Inc., Milwaukee, WI

Contracting Activity: General Services Administration, New York, NY

NSN(s)—Product Name(s):

7110–00–194–1611—Rotary Drafting Stool—Faux Leather
7110–00–281–4469—Rotary Drafting Stool—Upholstered

Contracting Activity: General Services Administration, Philadelphia, PA

NSN(s)—Product Name(s):

7210–00–NIB–0160—Pillow, Medical, White, 26″ x 20″
7210–00–NIB–0161—Pillow, Medical, Blue, 26″ x 20″
7210–00–NIB–0162—Pillow, Bed, Flame Resistant, Pink, 26″ x 20″

Mandatory Source(s) of Supply: Blind Industries & Services of Maryland, Baltimore, MD

Contracting Activity: Department of Veterans Affairs

NSN(s)—Product Name(s): 5970–01–245–7042—Tape, Electrical Insulation, Black, 1″ W x 108 ft

Mandatory Source(s) of Supply: Cincinnati Association for the Blind, Cincinnati, OH; Blind Industries & Services of Maryland, Baltimore, MD

NSN(s)—Product Name(s): 5970–01–560–5355—Tape, Insulation, Electrical, High Voltage, Black, 2″ x 108′

Mandatory Source(s) of Supply: Blind Industries & Services of Maryland, Baltimore, MD

Contracting Activity: Defense Logistics Agency Aviation

Services:

Service Type: Administrative/General Support Service

Mandatory for: GSA, Southwest Supply Center, 819 Taylor Street, Fort Worth, TX

Mandatory Source(s) of Supply: The Lighthouse for the Blind in New Orleans, Inc., New Orleans, LA

Contracting Activity: General Services Administration, FPDS Agency Coordinator

Service Type: Operation of Postal Service Center Service

Mandatory for: Luke Air Force Base, 14185 Falcon St, Luke AFB, AZ

Mandatory Source(s) of Supply: Arizona Industries for the Blind, Phoenix, AZ

Contracting Activity: Dept of the Air Force, FA7014 AFDW PK

Barry S. Lineback,
Director, Business Operations.

[FR Doc. 2016–16783 Filed 7–14–16; 8:45 am]

BILLING CODE 6353–01–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List: Additions

AGENCY: Committee for Purchase From People Who are Blind or Severely Disabled.

ACTION: Additions to the Procurement List.

SUMMARY: This action adds products to the Procurement List that will be furnished by a nonprofit agency employing persons who are blind or have other severe disabilities.

DATES: Effective 8/14/2016.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, 1401 S. Clark Street, Suite 715, Arlington, Virginia, 22202–4149.

FOR FURTHER INFORMATION CONTACT: Barry S. Lineback, Telephone: (703) 603–7740, Fax: (703) 603–0655, or email *CMTEFedReg@AbilityOne.gov.*

SUPPLEMENTARY INFORMATION:

Additions

On 5/6/2016 (81 FR 27419–27420) and 5/20/2016 (81 FR 31917–31918), the Committee for Purchase from People Who are Blind or Severely Disabled published notices of proposed additions to the Procurement List.

After consideration of the material presented to it concerning capability of qualified nonprofit agencies to provide the products and impact of the additions on the current or most recent contractors, the Committee has determined that the products listed below are suitable for procurement by the Federal Government under 41 U.S.C. 8501–8506 and 41 CFR 51–2.4.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organization that will furnish the products to the Government.

2. The action will result in authorizing a small entity to furnish the products to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 8501–8506) in connection with the products proposed for addition to the Procurement List.

End of Certification

Accordingly, the following products are added to the Procurement List:

Products:

NSN(s)—Product Name(s):

6135–00–826–4798—Battery, Non-Rechargeable, AAA, Alkaline
6135–00–985–7845—Battery, Non-Rechargeable, AA, Alkaline
6135–00–835–7210—Battery, Non-Rechargeable, D, Alkaline

Mandatory for: Total Government Requirement

Mandatory Source(s) of Supply: Eastern Carolina Vocational Center, Inc., Greenville, NC

Contracting Activity: Defense Logistics Agency Land and Maritime

Distribution: A-List

Barry S. Lineback,
Director, Business Operations.

[FR Doc. 2016–16784 Filed 7–14–16; 8:45 am]

BILLING CODE 6353–01–P

BUREAU OF CONSUMER FINANCIAL PROTECTION

Supervisory Highlights: Mortgage Servicing Special Edition 2016

AGENCY: Bureau of Consumer Financial Protection.

ACTION: Supervisory Highlights; notice.

SUMMARY: The Bureau of Consumer Financial Protection (CFPB) is issuing its eleventh edition of its Supervisory Highlights. In this issue, the CFPB shares findings from supervisory examination work in mortgage servicing between January 2014 and April 2016. The issue also discusses Supervision's approach mortgage to servicing exams, including a description of recent changes to the mortgage servicing chapter of the CFPB Supervision and Examination Manual.

DATES: The Bureau released this edition of the *Supervisory Highlights* on its Web site on June 22, 2016.

FOR FURTHER INFORMATION CONTACT: Christopher J. Young, Managing Senior Counsel and Chief of Staff, Office of Supervision Policy, 1700 G Street NW., 20552, (202) 435–7408.

SUPPLEMENTARY INFORMATION:

1. Introduction

Mortgage servicers play a central role in homeowners' lives by managing their mortgage loans. Servicers collect and apply payments, work out modifications to loan terms, and handle the difficult process of foreclosure. As the financial crisis made clear, weak customer support, lost paperwork, and mishandled accounts can lead to many wrongful foreclosures and other serious harm. Since consumers do not choose their mortgage servicers they cannot take their business elsewhere.

To improve practices in the servicing market, the Dodd-Frank Act Wall Street Reform and Consumer Protection Act (Dodd-Frank Act) imposed new requirements on servicers and gave the Consumer Financial Protection Bureau (CFPB) the authority to implement those new requirements and adopt additional rules to protect consumers. The CFPB released rules, effective January 10, 2014, to improve the information consumers receive from their servicers, to enhance the protections available to consumers to address servicer errors, and to establish baseline servicing requirements that provide additional protections for consumers who have fallen behind on their mortgage payments. Supervisory examinations of mortgage servicers now generally focus on reviewing for compliance with these servicing rules and for unfair, deceptive, and abusive acts or practices.

To assist industry in its efforts to comply Federal consumer financial law, this Special Edition of *Supervisory Highlights* discusses recent supervisory examination observations in mortgage servicing. To provide additional context for readers, we integrate these recent observations with observations from previous editions of *Supervisory Highlights* by subject matter.[1]

The magnitude and persistence of compliance challenges since 2014, particularly in the areas of loss mitigation and servicing transfers, show that while the servicing market has made investments in compliance, those investments have not been sufficient across the marketplace. Outdated and deficient servicing technology continues to pose considerable risk to consumers in the wider servicing market. These shortcomings are compounded by lack of proper training, testing, and auditing of technology-driven processes, particularly to handle more individualized situations related to delinquencies and loss mitigation processes. None of these problems is insurmountable, however, with the proper focus on making necessary improvements, especially in the information technology systems necessary for effective implementation. Supervisory examinations do show that some servicers have significantly improved their compliance positions, and this edition concludes by sharing how these servicers have strengthened their compliance.

2. Our Approach to Mortgage Servicing Examinations

To determine which mortgage servicers to examine, we use a prioritization framework that considers a broad range of factors to predict the likelihood of consumer harm.[2] For instance, because a servicer's market share corresponds to the number of consumers affected, we prioritize relatively larger servicers with a more dominant market presence over comparatively smaller servicers.

Our prioritization approach counterbalances this size consideration with what we call field and market intelligence. We consider qualitative and quantitative factors for each servicer such as the strength of compliance management systems, the existence of other regulatory actions, findings from our prior examinations, servicing transfer activity, the number, severity and trends of consumer complaints, as well as input from housing counselors and other stakeholders about institutional performance based on their experience.

In fall 2011, we published the initial mortgage servicing chapter of the CFPB Supervision and Examination Manual. We update the manual periodically, most recently in May 2016, to reflect regulatory changes, to make technical corrections and to update examination priorities.[3] In the latest version, we enhance the section related to consumer complaints to highlight that for mortgage servicers, examiners will be reviewing whether the servicer has an adequate process for expedited evaluation of complaints or notices of error for borrowers or borrower advocates alleging regulatory compliance issues where the borrower is facing imminent foreclosure. The possibility of foreclosure puts even more weight on the importance of an appropriate complaint escalation process, which is essential to any compliance management system.[4]

Generally, our examinations review compliance management systems and evaluate compliance through transaction testing of specific loan files. In many instances, examiners conduct specific transaction testing based on consumer complaints submitted to housing counselors or the CFPB's Office of Consumer Response, particularly where the servicer did not provide a sufficient response or remedy. The scope for the content of our examinations reflects the size and risk profile of each servicer, and as a result, the content of our transaction testing may vary across market participants.

Our supervisory work also has included use of the Equal Credit Opportunity Act (ECOA) Baseline Modules, which are part of the CFPB

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[1] Observations shared in previous editions of *Supervisory Highlights* will be footnoted. Questions or comments may be directed to *CFPB_Supervision@cfpb.gov.*

[2] See *Supervisory Highlights:* Summer 2013, Section 3.2.3, input from housing counselors and other stakeholders.

[3] See CFPB Supervision and Examination Manual, *available at http://files.consumerfinance.gov/f/201401_cfpb_mortgage-servicing-exam-procedures.pdf.*

[4] See page CMR 10 "Consumer Complaint Response" in the CFPB Supervision and Examination Manual, *available at: http://files.consumerfinance.gov/f/201210_cfpb_supervision-and-examination-manual-v2.pdf.*

Supervision and Examination Manual. Examination teams use these modules to conduct ECOA Baseline Reviews, which evaluate how well institutions' compliance management systems identify and manage fair lending risks. The module 4, covering fair lending risks related to servicing, includes questions on such topics as fair lending training of servicing staff, fair lending monitoring of servicing, and servicing consumers with Limited English Proficiency. Based on the information gathered through these ECOA Baseline Reviews, and other inputs used in our prioritization process, Supervision will be conducting more comprehensive ECOA Targeted Reviews of mortgage servicers in 2016.

Where we observe more significant violations during an examination, we may refer matters to our Action Review Committee.[5] The committee uses a deliberative and rigorous process to determine whether matters that originate from our examinations will be resolved through confidential supervisory action, such as a board resolution or memorandum of understanding, or through a public enforcement action. In determining the appropriate action, the committee considers a variety of factors, including the magnitude of consumer harm, whether the violation was self-identified, and the timeliness and scope of remediation.

Additionally, we have identified potential risk areas and provided general compliance suggestions related to mortgage servicing by publishing several compliance bulletins. The bulletins issued to date have covered the following topics: Permanent Change of Station Orders,[6] Mortgage Servicing Transfers,[7] and Private Mortgage Insurance Cancellation and Termination.[8]

3. Supervisory Observations

In examining for compliance with the servicing rules, Supervision has addressed issues across servicing business areas, and most extensively in the areas of loss mitigation acknowledgement notices (3.1); loss mitigation offers and related communications (3.2); loan modification denial notices (3.3); policies and procedures (3.4); and servicing transfers (3.5). The following findings reflect information obtained from supervisory activities as captured in examination reports or supervisory letters. In some instances, not all corrective actions, including through enforcement, have been completed at the time of this report's publication.

3.1. Loss Mitigation Acknowledgement Notices

Before the new servicing rules, gaps in servicer communication and coordination kept many distressed consumers in the dark about available options to avoid foreclosure. Consumers who applied for such options sometimes found themselves stuck in a cycle of lost paperwork and redundant document requests while their foreclosure dates grew nearer.

To address this set of issues, the servicing rules now require that if a servicer receives a loss mitigation application 45 days or more before a foreclosure sale, it must notify the borrower in writing within five days to acknowledge receipt of the application and whether it is complete or incomplete.[9] If incomplete, the notice must state the additional documents and information the borrower must submit to complete the application and a reasonable date by which the borrower should submit those documents and information.[10]

CFPB examiners have found multiple violations related to these critical process requirements. Examiners found that one or more servicers failed to send any loss mitigation acknowledgment notices due to a repeated loss mitigation processing platform malfunction over a significant period of time. Supervision cited the servicer(s) for violating Regulation X and directed the servicer(s) to remediate affected borrowers, including for interest, fees, and any additional harm incurred.[11] Supervision also directed the servicer(s) to fix and monitor the servicing platform for compliance weaknesses. Supervision later confirmed that the servicer(s) undertook appropriate corrective actions.

Supervision also found deceptive statements in loss mitigation acknowledgement notices. One or more servicers sent acknowledgement notices that represented homes would not be foreclosed on before the deadline passed for submitting missing documents. But the servicer(s) foreclosed on homes before the submission deadline. Supervision determined the representations to be deceptive, independent of whether or not the servicing rules permitted the servicer(s) to foreclose on the specific borrower(s) at that time. Supervision directed the servicer(s) to undertake remedial and corrective actions which are under review.[12]

Supervision also observed deficiencies with the timeliness and content of acknowledgment notices. One or more servicers sent acknowledgement notices more than five days after receiving a borrower's loss mitigation application. And at one or more servicers, the noncompliant acknowledgment notices for incomplete loss mitigation applications:

- Failed to state the additional documents and information for borrowers to submit to complete the application, such as income and tax forms that the servicer's internal records showed were necessary at that time,. Instead, the servicer(s) separately requested the necessary documents several weeks after the acknowledgment notice.
- Requested documents, sometimes dozens in number, inapplicable to borrower circumstances and which were not needed to evaluate borrowers for loss mitigation.[13]
- Requested documents that borrowers already submitted.
- Failed to include any reasonable date by which borrowers must return additional documents and information.
- Gave borrowers 30 days to submit additional documents, but the servicer(s) then denied borrowers' applications for loss mitigation before 30 days.[14]
- Failed to include a statement that borrowers should consider contacting servicers of any other mortgage loans

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[5] See *Supervisory Highlights:* Summer 2015, Section 3.1.4, *available at http://files.consumerfinance.gov/f/201506_cfpb_supervisory-highlights.pdf.*

[6] See Interagency Guidance on Mortgage Servicing Practices Concerning Military Homeowners with Permanent Change of Station Orders, *available at http://files.consumerfinance.gov/f/201206_cfpb_PCS_Orders_Guidance.pdf.*

[7] See CFPB Bulletin 2014–01 (Aug. 19, 2014), *available at http://files.consumerfinance.gov/f/201408_cfpb_bulletin_mortgage-servicing-transfer.pdf.*

[8] See CFPB Bulletin 2015–03 (Aug. 4, 2015), *available at http://files.consumerfinance.gov/f/201508_cfpb_compliance-bulletin_private-mortgage-insurance-cancellation-and-termination.pdf.*

[9] 12 CFR 1024.41(b)(2)(i)(B).

[10] Id. The acknowledgment notice also must include a statement that the borrower should consider contacting servicers of any other mortgage loans secured by the same property to discuss available loss mitigation options.

[11] 12 CFR 1024.41(b)(2)(i)(B). Previously discussed in the Summer 2015 edition of *Supervisory Highlights, available at http://files.consumerfinance.gov/f/201506_cfpb_supervisory-highlights.pdf.*

[12] 12 U.S.C. 5536(a)(1)(B).

[13] Previously discussed in the Summer 2015 edition of *Supervisory Highlights, available at http://files.consumerfinance.gov/f/201506_cfpb_supervisory-highlights.pdf.*

[14] Previously discussed in the Fall 2015 edition of *Supervisory Highlights, available at http://files.consumerfinance.gov/f/201506_cfpb_supervisory-highlights.pdf.*

secured by the same property to discuss available loss mitigation options.

Supervision cited the servicer(s) above for violating Regulation X and directed them to revise deficient acknowledgement notices to meet Regulation X requirements.[15]

3.2 Loss Mitigation Offer Letters and Related Communications

Supervision also found serious violations of Federal consumer financial law with servicer loss mitigation offer letters, loss mitigation offers, and related communications. In offering proprietary modifications, one or more servicers engaged in deceptive and abusive practices in connection with communicating whether and when outstanding fees, charges, and advances would be assessed. Specifically, one or more servicers engaged in a deceptive practice by misrepresenting to borrowers that it would defer such charges to the maturity date of the loan, when in fact it often assessed hundreds of dollars in these charges after the borrowers signed and returned the permanent modification agreements. Additionally, one or more servicers took unreasonable advantage of borrowers' lack of understanding of the material risks of the loan modification and took unreasonable advantage of borrowers' inability to protect their interests in selecting or using the modification because the language in the proprietary modification offer made it impossible for a borrower to understand the true nature of how and when these charges would be assessed. Without such knowledge, a borrower could not have understood the material risks of the modification, nor could he adequately protect himself from the potential payment shock from the assessment of such charges. Supervision cited the servicer(s) for deceptive and abusive practices and required the servicer(s) to provide accurate information regarding fee assessment practices about its proprietary loss mitigation options to borrowers.[16]

Furthermore, one or more servicers sent loss mitigation offer letters with response deadlines that had already passed or were about to pass by the time the borrower received the letter. The servicer(s) generated the letters in timely fashion, but delayed sending them to borrowers for a substantial number of days. Supervision cited this practice as unfair and directed the servicer(s) to undertake remedial and corrective actions which are under review.[17]

With respect to permanent modification agreements, one or more servicers sent agreements to some borrowers that did not match the terms approved by its underwriting software. Many borrowers signed and returned the agreements, but then the agreements were not executed by the servicer(s). Instead, after substantial delays, the servicer(s) sent updated modification agreements with materially different terms to the borrowers. These misrepresentations about the available terms affected the ultimate payments the borrowers would make, influencing both whether they would accept the modification and how they could subsequently budget based on their expected payment. Supervision determined that the servicer(s) engaged in a deceptive practice in connection with these modifications and directed the servicer(s) to undertake remedial and corrective actions, which are under review.[18]

One or more servicers represented in loan modification trial period plans that borrowers would receive a permanent modification after making three trial payments. However, after borrowers made the required trial payments, the servicer(s) could still deny the permanent modification based on the results of a title search. The servicer(s) did not communicate to borrowers that permanent loan modifications were contingent on a title search in the trial period offer letter. Supervision determined the practice to be deceptive and directed the servicer(s) to provide accurate information to borrowers about loss mitigation options.[19]

Against investor guidelines, one or more servicers treated borrower self-employed gross income as net income when evaluating loss mitigation applications. The practice inflated borrower income and may have led to less affordable modifications. Supervision traced the practice to an underwriting error and cited the servicer(s) for violating Regulation X.[20] It directed the servicer(s) to conduct training for loss mitigation personnel to calculate self-employment income according to investor guidelines.

One or more servicers failed to convert a substantial number of trial modifications to permanent modifications timely after borrowers successfully completed trial modifications. The delays harmed borrowers who then owed higher amounts of accrued interest under the finalized permanent modifications than they would have owed under a timely conversion. During the delay, the interest accrued at the original contractual rate, rather than at the lower rate provided under the modification's terms. The servicer then capitalized the additional interest into the principal balance owed under the permanent modification. The servicer(s) also continued to report borrowers that had been delinquent at the beginning of their trial modifications as delinquent to the consumer reporting agencies during the length of the delay. Some affected borrowers filed complaints with the CFPB's Office of Consumer Response describing how the uncertainty of the loan modification decisions hurt their ability to plan for the future. Supervision determined that the substantial delays, combined with the negative consequences attributable to the delays, constituted an unfair practice and directed the servicer(s) to undertake remedial and corrective actions which are under review.[21]

Supervision found a deceptive practice related to how one or more servicers disclosed the terms of a payment plan that deferred mortgage payments for daily simple interest mortgage loans.[22] The communications included misleading representations about the deferments, which represented that deferred interest would be repayable at the end of the loan term when, in fact, the servicer collected the deferred interest from consumer immediately after the deferment ended. Supervision directed the servicer(s) to clearly disclose how interest accrues while on the plan and its impact on monthly payments after the deferment period concludes.

Supervision found that one or more servicers sent notices warning that foreclosure would be imminent to borrowers who were current on their low-balance home equity lines of credit (HELOCs) and no monthly payment due. Supervision cited the practice as deceptive and directed servicer(s) to cease sending collection letters that misled consumers into believing that the loans were delinquent.[23]

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[15] 12 CFR 1024.41(b)(2)(i)(B).

[16] 12 U.S.C. 5536(a)(1)(B)

[17] 12 U.S.C. 5536(a)(1)(B).

[18] 12 U.S.C. 5536(a)(1)(B). Previously discussed in the Fall 2014 edition of *Supervisory Highlights*, *available at http://files.consumerfinance.gov/f/201410_cfpb_supervisory-highlights_fall-2014.pdf.*

[19] 12 U.S.C. 5536(a)(1)(B).

[20] 1024.41(c)(1)(i).

[21] 12 U.S.C. 5536(a)(1)(B). Previously discussed in the Fall 2014 edition of *Supervisory Highlights*, *available at http://files.consumerfinance.gov/f/201410_cfpb_supervisory-highlights_fall-2014.pdf.*

[22] 12 U.S.C. 5536(a)(1)(B). Previously discussed in the Summer 2015 edition of *Supervisory Highlights*, *available at http://files.consumerfinance.gov/f/201506_cfpb_supervisory-highlights.pdf.*

Additionally, Supervision has repeatedly identified waivers of consumer rights in loss mitigation agreements. Regulation Z states that a "contract or other agreement relating to a consumer credit transaction secured by a dwelling . . . may not be applied or interpreted to bar a consumer from bringing a claim in court pursuant to any provision of law for damages or other relief in connection with any alleged violation of any Federal law." [24] Examiners found one or more servicers required borrowers to sign waivers agreeing that they would have no "defenses, set-offs, or counterclaims to the indebtedness of borrowers pursuant to the Loan Document" in order to enter mortgage repayment and loan modification plans. Defenses, set-offs, and counterclaims pertain to a contract or other agreement to a consumer credit transaction secured by a dwelling. As borrowers were likely to read the waiver as barring them from bringing claims—including Federal claims—related to their mortgage, Supervision cited the waiver language as deceptive and directed the servicer(s) to remove it from all loss mitigation agreements.[25]

3.3 Loan Modification Denial Notices

Where servicers deny complete loss mitigation applications for any trial or permanent loan modification option, denial notices help borrowers understand the reasons and, where appropriate, provide relevant information about the appeals process. Generally, the servicing rules require that denial notices provide the specific reason or reasons for denying the borrower the trial or permanent loan modification option and, if applicable, that the borrower was not evaluated on other criteria. The rules enable a borrower to appeal a denial of a trial or permanent loan modification option so long as the borrower's complete loss mitigation application is received 90 days or more before a foreclosure sale or during the pre-foreclosure review period.[26]

Supervision found that denial notices at one or more servicers failed to state the correct reason(s) for denying a trial or permanent loan modification option as required by Regulation X.[27] For example, the notices' denial reason stated that the borrower "did not provide the requested additional information needed to complete the workout review." However, the servicer(s) platform indicated that the borrower's application was complete and was instead denied for a specific reason related to the borrower's income.

One or more servicers' notices also stated "Not Available*" as the reason for denying loss mitigation applications. The asterisk elaborated: "Not Available means this program was not considered due to an eligibility requirement or requirements not met."

Supervision cited the two practices above for violating Regulation X and directed the servicer(s) to state the specific reason or reasons for its denial of each trial or permanent loan modification option and, if applicable, that the borrower was not evaluated on other criteria.[28]

When a borrower has the right to appeal the denial of a trial or permanent loan modification, a servicer must, in its notice after evaluating the borrower's complete loss mitigation application, inform the borrower of the appeal right and the amount of time the borrower has to file the appeal.[29] One or more servicers sent denial notices that failed to communicate a borrower's specific right to appeal. The notices instead generically stated that the borrower may have a right to appeal if the borrower met certain requirements. Supervision cited servicer(s) for violating Regulation X and directed the servicer(s) to include more specific appeal language in their denial letters where appropriate, rather than only generic appeal language in all instances.[30]

3.4 Servicing Policies, Procedures, and Requirements

To undergird the loss mitigation application process, Regulation X requires servicers to maintain policies and procedures reasonably designed to achieve specific objectives that include: Providing timely and accurate information; properly evaluating loss mitigation applications; facilitating oversight of and compliance by service providers; and facilitating transfer of information during servicing transfers.[31] In reviewing for these requirements, Supervision found that one or more servicers violated Regulation X because their policies and procedures were not reasonably designed to achieve the following objectives:

- Providing a borrower with accurate and timely information and documents in response to the borrower's requests for information with respect to the borrower's mortgage loan. One or more servicers failed to provide information and loss mitigation application forms to a substantial number of borrowers who called in to request such information.[32]
- Upon the death of a borrower, promptly identifying and facilitating communication with the successor in interest of the deceased borrower with respect to the property secured by the deceased borrower's mortgage loan.[33] One or more servicers required probate for borrowers to establish themselves as successors in states where probate was not required.
- Identifying with specificity all loss mitigation options for which a borrower may be eligible pursuant to any requirements established by an owner or assignee of the borrower's mortgage loan.[34] One or more servicers sent letters to borrowers soliciting loss mitigation applications when internal records showed that the borrowers were not eligible for any loss mitigation option.[35]
- Providing prompt access to all documents and information submitted by a borrower in connection with a loss mitigation option to servicer personnel assigned to assist the borrower under the rules.[36] One or more servicers failed to identify and process material submitted by borrowers to complete a loss mitigation application. The servicer(s) permitted borrowers to send material through fax, but lacked policies and procedures for date-stamping, cataloging and distributing loss mitigation material to appropriate departments, which resulted in servicer personnel assigned to assist the borrower under the rules being unable to access relevant information in a timely way.
- Properly evaluating a loss mitigation application for all options for which the borrower may be eligible based on the loan owner's requirements.[37] One or more servicers evaluated applications only for the loss mitigation options preselected by

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[23] 12 U.S.C. 5536(a)(1)(B). Previously discussed in the Summer 2015 edition of *Supervisory Highlights, available at http://files.consumerfinance.gov/f/201506_cfpb_supervisory-highlights.pdf.*

[24] 12 CFR 1026.36(h)(2).

[25] 12 U.S.C. 5536(a)(1)(B). Previously discussed in the Fall 2015 edition of *Supervisory Highlights, available at http://files.consumerfinance.gov/f/201506_cfpb_supervisory-highlights.pdf.*

[26] 12 CFR 1024.41(d), (h).

[27] 12 CFR 1024.41(d).

[28] 12 CFR 1024.41(d).

[29] 12 CFR 1024.41(c)(1)(ii).

[30] 12 CFR 1024.41(c)(1)(ii). Previously discussed in the Fall 2015 edition of *Supervisory Highlights, available at http://files.consumerfinance.gov/f/201506_cfpb_supervisory-highlights.pdf.*

[31] 12 CFR 1024.38(a), (b).

[32] 12 CFR 1024.38(b)(1)(iii).

[33] 12 CFR 1024.38(b)(1)(vi).

[34] 12 CFR 1024.38(b)(2)(ii).

[35] Reported in the Fall 2015 edition of *Supervisory Highlights, available at http://files.consumerfinance.gov/f/201506_cfpb_supervisory-highlights.pdf.*

[36] 12 CFR 1024.38(b)(2)(iii).

[37] 12 CFR 1024.38(b)(2)(v).

servicer personnel and not for all options available to the borrower.[38]

- Facilitating the sharing of accurate and current information regarding the status of any evaluation of a borrower's loss mitigation application and the status of any foreclosure proceeding among appropriate servicer personnel, including service provider personnel. One or more servicer(s)' foreclosure attorneys sent a foreclosure referral letter to the borrower after the borrower entered into a loss mitigation agreement with the servicer.[39]
- As a transferee servicer, ensuring that it can identify necessary documents or information that may not have been transferred by a transferor and obtain such documents from the transferor servicer. One or more transferee(s) failed to identify necessary documents, including loss mitigation agreements and mortgage notes not transmitted by the transferor.[40]

In the above cases where Supervision detected policies, procedures, or requirements not in compliance with Regulation X, Supervision directed servicers to implement policies, procedures, and requirements compliant with the Rule and to monitor for their effectiveness.

3.5 *Servicing Transfers*

Transferring loans during the loss mitigation process heightens risks to consumers, including the risk that documents and information might not be accurately transferred.[41] While Supervision has observed more attention to pre-transfer planning by transferor and transferee servicers since 2014, Supervision found that at one or more servicers incompatibilities between servicer platforms led, in part, to transferees failing to identify and honor in-place loss mitigation after receiving the loans.

Additionally, one or more servicers failed to honor the terms of in-place trial modifications after transfer. Some borrowers who completed trial payments with the new servicer nevertheless encountered substantial delays before receiving a permanent loan modification. Supervision concluded that the delay caused substantial injury as trial payments were less than the amounts required by the promissory note, and consumers continuing to make trial payments while waiting for the permanent modification accrued interest on the unpaid principal balance. Such delays were exacerbated by the transferee(s)' failure to obtain timely access to an online workout tool required by the investor. Supervision cited this practice as unfair and directed the transferee servicers(s) to develop and implement policies, procedures, training, and audits to promptly identify and honor prior loss mitigation agreements, whether completed or in-flight at the time of transfer.[42]

Supervision also observed some servicers improve transfer policies, procedures, and practices. For example, in response to Supervision's direction to one or more transferee servicers to identify in-flight modifications, the transferee(s) began to use certain tools generally available to industry participants—the HomeSavers Solutions Network and the HAMP Reporting Tool—to reconcile loan data during transfer. Supervision noted that this approach gave transferee(s) the ability to identify more in-flight modifications. Despite this improvement, Supervision observed that transferee(s) still failed to recognize modifications not registered by the transferor or not otherwise in the databases and could benefit from conducting a post-transfer review for in-flight loss mitigation. The transferee(s) agreed to further enhance transfer protocols.

Also in connection with servicing transfers, one or more transferee(s) found that delays in honoring in-flight modifications were caused by their dependence on the information technology department to manually override data fields whenever the servicing platform rejected transferor data. By granting override authority to loss mitigation staff, the transferee(s) reduced the time required to honor in-flight modifications.

4. Conclusion

While Supervision continues to be concerned about the range of legal violations identified at various mortgage servicers, it also recognizes efforts made by certain servicers to properly staff effective compliance management programs. Some servicers have made significant improvements in the last several years, in part by enhancing and monitoring their servicing platforms, staff training, coding accuracy, auditing, and allowing for greater flexibility in operations. More generally, Supervision found compliance audits that thoroughly assessed the business unit's internal control environment, clearly identified issues with compliance, detailed management's response, set a target date for resolving the identified issues, and completed the necessary adjustments promptly. At one or more servicers, these audits included reviews of service providers and were part of a wider and appropriately resourced compliance framework. One or more servicers also conducted formal reviews of information technology structures that identified the root causes of earlier compliance weaknesses, including platform outages. These reviews led the servicer(s) to replace outdated technology, such as document management systems.

Supervision also observed that servicers are actively reviewing complaints for allegations of law violations. One or more servicers used analytic tools to search, review, and track complaint records with content indicating regulatory violations. One or more servicers also created a complaint governance committee to oversee all customer complaints to ensure they receive appropriate engagement, including remediation as appropriate. One or more servicers also designated management level employees as primary contacts for Federal and State regulators and other government bodies for discussing complaints and inquiries from borrowers who are in default or have applied for loan modifications.

As the above observations show, improvements and investments in servicing technology, staff training, and monitoring can be essential to achieving an adequate compliance position. However, such improvements have not been uniform across market participants and Supervision continues to observe compliance risks, particularly in the areas of loss mitigation and servicing transfers. A growing point of emphasis for Supervision in achieving needed improvements in servicer compliance will be to require servicers to submit specific and credible plans describing how changes in their information technology systems will offer assurance that they can systematically and effectively implement the changes made to resolve the issues identified by Supervision.

6. Regulatory Requirements

This *Supervisory Highlights* summarizes existing requirements under the law, summarizes findings made in the course of exercising the

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[38] Reported in the Fall 2015 edition of *Supervisory Highlights, available at http://files.consumerfinance.gov/f/201506_cfpb_supervisory-highlights.pdf.*

[39] 12 CFR 1024.38(b)(3)(iii). Reported in the Fall 2015 edition of *Supervisory Highlight, available at http://files.consumerfinance.gov/f/201506_cfpb_supervisory-highlights.pdf.*

[40] 12 CFR 1024.38(b)(4)(ii).

[41] *See* CFPB Bulletin 2014–01 (Aug. 19, 2014), *available at http://files.consumerfinance.gov/f/201408_cfpb_bulletin_mortgage-servicing-transfer.pdf.*

[42] 12 U.S.C. 5536(a)(1)(B). Previously discussed in the Sumer 2015 edition of Supervisory Highlights, *available at http://files.consumerfinance.gov/f/201506_cfpb_supervisory-highlights.pdf.*

Bureau's supervisory and enforcement authority, and is a non-binding general statement of policy articulating considerations relevant to the Bureau's exercise of its supervisory and enforcement authority. It is therefore exempt from notice and comment rulemaking requirements under the Administrative Procedure Act pursuant to 5 U.S.C. 553(b). Because no notice of proposed rulemaking is required, the Regulatory Flexibility Act does not require an initial or final regulatory flexibility analysis. 5 U.S.C. 603(a), 604(a). The Bureau has determined that this *Supervisory Highlights* does not impose any new or revise any existing recordkeeping, reporting, or disclosure requirements on covered entities or members of the public that would be collections of information requiring OMB approval under the Paperwork Reduction Act, 44 U.S.C. 3501, *et seq.*

Dated: June 22, 2016.

Richard Cordray,

Director, Bureau of Consumer Financial Protection.

[FR Doc. 2016–16786 Filed 7–14–16; 8:45 am]

BILLING CODE 4810–AM–P

DEPARTMENT OF DEFENSE

Department of the Army

Inland Waterways Users Board; Request for Nominations

AGENCY: Department of the Army, U.S. Army Corps of Engineers, DOD.

ACTION: Notice of request for nominations.

SUMMARY: The Department of the Army is publishing this notice to request nominations to serve as representatives on the Inland Waterways Users Board, sponsored by the U.S. Army Corps of Engineers. Section 302 of Public Law 99–662 established the Inland Waterways Users Board. The Board is an independent Federal advisory committee. The Secretary of the Army appoints its 11 (eleven) representative organizations. This notice is to solicit nominations for 11 (eleven) appointments for terms that will begin by May 27, 2017. For additional information about the Board, please visit the committee's Web site at *http://www.iwr.usace.army.mil/Missions/Navigation/InlandWaterwaysUsersBoard.aspx.*

ADDRESSES: Institute for Water Resources, U.S. Army Corps of Engineers, ATTN: Mr. Mark R. Pointon, Designated Federal Officer (DFO) for the Inland Waterways Users Board, CEIWR–GM, 7701 Telegraph Road, Casey Building, Alexandria, VA 22315–3868; by telephone at 703–428–6438; and by email at *Mark.Pointon@usace.army.mil.*

FOR FURTHER INFORMATION CONTACT: Alternatively, contact Mr. Kenneth E. Lichtman, the Alternate Designated Federal Officer (ADFO), in writing at the Institute for Water Resources, U.S. Army Corps of Engineers, ATTN: CEIWR–GW, 7701 Telegraph Road, Casey Building, Alexandria, VA 22315–3868; by telephone at 703–428–8083; and by email at *Kenneth.E.Lichtman@usace.army.mil.*

SUPPLEMENTARY INFORMATION: The selection, service, and appointment of representative organizations to the Board are covered by provisions of section 302 of Public Law 99–662. The substance of those provisions is as follows:

a. Selection. Representative organizations are to be selected from the spectrum of commercial carriers and shippers using the inland and intracoastal waterways, to represent geographical regions, and to be representative of waterborne commerce as determined by commodity ton-miles and tonnage statistics.

b. Service. The Board is required to meet at least semi-annually to develop and make recommendations to the Secretary of the Army on waterways construction and rehabilitation priorities and spending levels for commercial navigation improvements, and report its recommendations annually to the Secretary and Congress.

c. Appointment. The operation of the Board and appointment of representative organizations are subject to the Federal Advisory Committee Act of 1972 (5 U.S.C., Appendix, as amended) and departmental implementing regulations. Representative organizations serve without compensation but their expenses due to Board activities are reimbursable. The considerations specified in section 302 for the selection of representative organizations to the Board, and certain terms used therein, have been interpreted, supplemented, or otherwise clarified as follows:

(1) Carriers and Shippers. The law uses the terms "primary users and shippers." Primary users have been interpreted to mean the providers of transportation services on inland waterways such as barge or towboat operators. Shippers have been interpreted to mean the purchasers of such services for the movement of commodities they own or control. Representative firms are appointed to the Board, and they must be either a carrier or shipper or both. For that purpose a trade or regional association is neither a shipper nor primary user.

(2) Geographical Representation. The law specifies "various" regions. For the purposes of the Board, the waterways subjected to fuel taxes and described in Public Law 95–502, as amended, have been aggregated into six regions. They are (1) the Upper Mississippi River and its tributaries above the mouth of the Ohio; (2) the Lower Mississippi River and its tributaries below the mouth of the Ohio and above Baton Rouge; (3) the Ohio River and its tributaries; (4) the Gulf Intracoastal Waterway in Louisiana and Texas; (5) the Gulf Intracoastal Waterway east of New Orleans and associated fuel-taxed waterways including the Tennessee-Tombigbee, plus the Atlantic Intracoastal Waterway below Norfolk; and (6) the Columbia-Snake Rivers System and Upper Willamette. The intent is that each region shall be represented by at least one representative organization, with that representation determined by the regional concentration of the firm's traffic on the waterways.

(3) Commodity Representation. Waterway commerce has been aggregated into six commodity categories based on "inland" ton-miles shown in Waterborne Commerce of the United States. These categories are (1) Farm and Food Products; (2) Coal and Coke; (3) Petroleum, Crude and Products; (4) Minerals, Ores, and Primary Metals and Mineral Products; (5) Chemicals and Allied Products; and (6) All Other. A consideration in the selection of representative organizations to the Board will be that the commodities carried or shipped by those firms will be reasonably representative of the above commodity categories.

d. Nomination. Reflecting preceding selection criteria, the current representation by the ten (10) organizations whose terms expire includes all Regions 1–6, all carrier and/or shipper representation and all commodity representation.

Individuals, firms or associations may nominate representative organizations to serve on the Board. Nominations will:

(1) Include the commercial operations of the carrier and/or shipper representative organization being nominated. This commercial operations information will show the actual or estimated ton-miles of each commodity carried or shipped on the inland waterways system in a recent year (or years), using the waterway regions and commodity categories previously listed.

(2) State the region(s) to be represented.

(3) State whether the nominated representative organization is a carrier, shipper or both.

(4) Provide the name of an individual to be the principle person representing the organization and information pertaining to their personal qualifications, to include a current biography or resume.

Previous nominations received in response to notices published in the **Federal Register** in prior years will not be retained for consideration. Renomination of representative organizations is required.

e. *Deadline for Nominations.* All nominations must be received at the address shown above no later than September 1, 2016.

Brenda S. Bowen,

Army Federal Register Liaison Officer.

[FR Doc. 2016–16699 Filed 7–14–16; 8:45 am]

BILLING CODE 3720–58–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Extension of Public Comment Period for Draft Environmental Impact Statement for the Continental United States Interceptor Site

AGENCY: Missile Defense Agency, Department of Defense.

ACTION: Notice of public comment period extension.

SUMMARY: The purpose of this notice is to announce an extension to the 45-day public comment period of the Notice of Availability for the Draft Environmental Impact Statement (EIS) for the potential deployment of a Continental United States (CONUS) Interceptor Site (CIS) published by the Missile Defense Agency (MDA) on May 31, 2016 (81 FR 34315–34316). The public comment period is extended 30 days and ends on August 17, 2016.

DATES: The extended 75-day public comment period for the Draft EIS began on June 3, 2016, with the publication of the Notice of Availability in the **Federal Register** by the U.S. Environmental Protection Agency (81 FR 35761–35762), and with this extension, will end on August 17, 2016.

ADDRESSES: Comments on the Draft EIS should be received by August 17, 2016 by one of the following methods:

- *Mail:* U.S. Postal Service to: Black & Veatch Special Projects Corp. Attn: MDA CIS EIS, 6800 W. 115th Street, Suite 2200, Overland Park, KS 66211–2420.
- *Email: MDA.CIS.EIS@BV.com.*

Public comments on the Draft EIS are requested pursuant to the NEPA. All written comments received during the comment period will become part of the public record. Providing private address information with your comment is voluntary and such personal information will be kept confidential unless release is required by law. All comments received by the public, including at public meetings, will be addressed in the Final EIS. A NOA will be published notifying the public of the final EIS.

FOR FURTHER INFORMATION CONTACT: Mr. Christopher Johnson, MDA Public Affairs, at 571–231–8212, or by email: *mda.info@mda.mil.* For more information, including a downloadable copy of the Draft EIS, visit the MDA Web site at *http://www.mda.mil.*

SUPPLEMENTARY INFORMATION:

Proposed Action and Alternative: The Department of Defense (DoD) does not have a proposed action and has not made a decision to deploy or construct an additional interceptor site. Current sites in Alaska and California provide the necessary protection of the homeland from a ballistic missile attack by countries such as North Korea and Iran. If the DoD were to make a decision in the future to construct a new site, the prior completion of the required site studies and EIS could shorten the timeline necessary to build such a site.

If deployed, a CIS would be an extension of the existing Ground-based Midcourse Defense (GMD) element of the Ballistic Missile Defense System. To the extent practicable, the CIS would be built as a contiguous Missile Defense Complex, similar to that found at Fort Greely, Alaska, and would consist of a deployment of up to a total of 60 Ground-Based Interceptors (GBIs) in up to three GBI fields. The GBIs would not be fired from their deployment site except in the Nation's defense and no test firing would be conducted at a CIS. The overall system architecture and baseline requirements for a notional CIS include, but are not limited to, the GBI fields, Command Launch Equipment, In-Flight Interceptor Communication System Data Terminals, GMD Communication Network, supporting facilities, such as lodging and dining, recreation, warehouse and bulk storage, vehicle storage and maintenance, fire station, hazardous materials/waste storage, and roads and parking where necessary.

Candidate site locations under consideration include: Fort Custer Training Center in Michigan; Camp Ravenna Joint Military Training Center in Ohio; and Fort Drum in New York. Earlier this year, MDA designated the Center for Security Forces Detachment Kittery Survival, Evasion, Resistance and Escape Facility (SERE East) in Redington Township, Maine, as an Alternative Considered, but Not Carried Forward. The Draft EIS also analyzed a No Action Alternative or no CIS deployment. The DoD has not made a decision to deploy or construct a CIS and does not have a preferred alternative.

For each of the candidate site locations, the following resource areas were assessed: Air quality, air space, biological, cultural, environmental justice, geology and soils, hazardous materials and hazardous waste management, health and safety, land use, noise, socioeconomics, transportation, utilities, water, wetlands, and visual and aesthetics.

Dated: July 11, 2016.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2016–16686 Filed 7–14–16; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DOD–2016–HA–0077]

Privacy Act of 1974; System of Records

AGENCY: Defense Health Agency, DoD.

ACTION: Notice to alter a system of records.

SUMMARY: The Defense Health Agency proposes to alter an existing system of records, EDHA 12, entitled "Third Party Collection System." This system is used to provide the Military Services medical billing, collections, and reporting processes for users at multiple locations, and to serve as the single source of financial information for the accounting of uniform business office accounts receivable.

DATES: Comments will be accepted on or before August 15, 2016. This proposed action will be effective the date following the end of the comment period unless comments are received which result in a contrary determination.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

* *Federal Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

* *Mail:* Department of Defense, Office of the Deputy Chief Management

Officer, Directorate of Oversight and Compliance, 4800 Mark Center Drive, Mailbox #24, Alexandria, VA 22350–1700. Instructions: All submissions received must include the agency name and docket number for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: Ms. Linda S. Thomas, Chief, Defense Health Agency Privacy and Civil Liberties Office, 7700 Arlington Boulevard, Suite 5101, Falls Church, VA 22042–5101, or by phone at (703) 275–6363.

SUPPLEMENTARY INFORMATION: The Defense Health Agency notices for systems of records subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address in **FOR FURTHER INFORMATION CONTACT** or at the Defense Privacy and Civil Liberties Division Web site at *http://dpcld.defense.gov/.*

The proposed system report, as required by 5 U.S.C. 552a(r) of the Privacy Act of 1974, as amended, was submitted on June 23, 2016, to the House Committee on Oversight and Government Reform, the Senate Committee on Governmental Affairs, and the Office of Management and Budget (OMB) pursuant to paragraph 4 of Appendix I to OMB Circular No. A–130, "Federal Agency Responsibilities for Maintaining Records About Individuals," revised November 28, 2000 (December 12, 2000 65 FR 77677).

Dated: July 11, 2016.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

EDHA 12

SYSTEM NAME:

Third Party Collection System (November 18, 2013, 78 FR 69076)

Changes

* * * * *

SYSTEM LOCATION:

Delete entry and replace with "Primary: General Dynamics Information Technology, Corporate Office Properties Trust (COPT) Data Center Solutions DC–6, 9651 Hornbaker Road, Manassas, VA 20109–3976.

Alternate: General Dynamics Information Technology, 11400 Westmoor Circle, Westminster, CO 80021–2735.

For a complete listing of all facility addresses write to the system manager."

Categories of individuals covered by the system:

Delete entry and replace with "Members of the Uniformed Services (including Reserve and National Guard personnel) and their dependents and retired military members and their dependents who receive or have received health services approved by DoD; contractors participating in military deployments or related operations who receive or have received medical or dental care at a military treatment facility (MTF); DoD civilian employees (to include non-appropriated fund employees), and other individuals who receive or have received medical or dental care at an MTF."

CATEGORIES OF RECORDS IN THE SYSTEM:

Delete entry and replace with "Individual Data: Patient name, DoD Identification Number (DoD ID Number), Social Security Number (SSN) (or foreign identification), citizenship, whether treatment was outpatient or inpatient, outpatient visit date and time, date of birth, address, email address, home and cell phone telephone numbers, gender, marital status, emergency contact information, driver's license number, family member prefix, and relationship to policy holder; sponsor or insurance policy holder name, SSN or DoD ID Number, and date of birth; other covered family member name(s), SSN, and date of birth; and, if applicable, Medicare and Medicaid coverage data.

Insurance Policy Information Data: Policy number or identification, card holder identification, group number, group name, enrollment plan/code, policy effective date, policy category, policy end date, insurance company name, address, and telephone number, insurance type, policy holder, and whether policy holder is insured through their employer; pharmacy insurance company name, address, and phone number, and pharmacy policy number, BIN number, and patient identification number.

Employer Information data: Employer name, address, and telephone number.

Billing Information Data: Bill type (MTF, clinic, pharmacy, laboratory/radiology, or ambulance), name and location of MTF, whether treatment was outpatient or inpatient, outpatient visit date and time, inpatient admission and discharge dates and time, patient identification number, patient name, provider code/description, office visit code description, Medical Expense and Performance Reporting System code/description, diagnosis code/description, billing amount, user who created the bill, date bill was created, status of bill, and source of billing data.

Accounting Information Data: Control number, transaction code, debit amount, credit amount, check number, batch posting number, balance, patient identification number, patient name, encounter date, comments, entry date, and follow-up date.

Insurance Company Data: Tables for insurance company, policy, provider, fees, codes, rates, and procedure maintenance."

AUTHORITY FOR THE MAINTENANCE OF THE SYSTEM:

Delete entry and replace with "10 U.S.C. 1079b, Procedures for charging fees for care provided to civilians; retention and use of fees collected; 10 U.S.C. 1095, Health care services incurred on behalf of covered beneficiaries: Collection from third-party payers; 42 U.S.C. Chapter 32, Third Party Liability For Hospital and Medical Care; 28 CFR part 43, Recovery of Costs of Hospital and Medical Care and Treatment Furnished by the United States; 32 CFR part 199, Civilian Health and Medical Program for the Uniformed Services (CHAMPUS); 32 CFR part 220, Collection from Third Party Payers of Reasonable Charges for Healthcare Services; DoD Instruction 6015.23, Foreign Military Personnel Care and Uniform Business Offices in Military Treatment Facilities (MTFs); and E.O. 9397 (SSN), as amended."

PURPOSE(S):

Delete entry and replace with "To provide the Military Services medical billing, collections, and reporting processes for users at multiple locations, and to serve as the single source of financial information for the accounting of uniform business office accounts receivable.

To assist the Defense Finance Accounting Service (DFAS) in collecting delinquent debts."

Routine uses of records maintained in the system, including categories of users and the purposes of such uses:

Delete entry and replace with "In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, as amended, these records may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

To interface with all commercial insurance carriers and parties against whom recovery has been sought by the DoD Military Health System (MHS), as well as all parties involved in support of the collection activities for health care approved by the DoD.

To the Departments of Treasury, Veterans Affairs, and Homeland Security in order to obtain reimbursement to the DoD for medical services provided by the MHS to beneficiaries and workforce members of such Departments.

To other persons or organizations, including other health insurers, Medicare, and Medicaid, who may be liable for payment for health care and medical services provided to an individual by the MHS.

To data clearinghouses for the purpose of converting the medical and pharmacy claims to an industry-wide format then forwarding to insurance companies (and other payers) electronically for payment.

Except as stipulated in NOTE 1 and NOTE 2 below, the DoD Blanket Routine Uses set forth at the beginning of the Defense Privacy and Civil Liberties Division compilation of systems of records notices may apply to this system. The complete list of DoD Blanket Routine Uses can be found online at: *http://dpcld.defense.gov/Privacy/SORNsIndex/BlanketRoutineUses.aspx*

NOTE 1: This system of records contains individually identifiable health information. The DoD Health Information Privacy Regulation (DoD 6025.18–R) or any successor DoD issuances implementing the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and 45 CFR parts 160 and 164, Health and Human Services, General Administrative Requirements and Security & Privacy, respectively, applies to most such health information. DoD 6025.18–R or a successor issuance may place additional procedural requirements on the uses and disclosures of such information beyond those found in the Privacy Act of 1974, as amended, or mentioned in this system of records notice.

NOTE 2: Records of identity, diagnosis, prognosis or treatment information of any patient maintained in connection with the performance of any program or activity relating to substance abuse education, prevention, training, treatment, rehabilitation, or research, which is conducted, regulated, or directly or indirectly assisted by a department or agency of the United States will be treated as confidential and disclosed only for the purposes and under the circumstances expressly authorized under 42 U.S.C. 290dd–2.''

Policies and practices for storing, retrieving, accessing, retaining, and disposing of records in the system:

STORAGE:

Delete entry and replace with ''Paper records and electronic storage media.''

RETRIEVABILITY:

Delete entry and replace with ''Patient name, SSN (or foreign identification) or DoD ID Number, insurance company name, date range, sponsor name, sponsor SSN or DoD ID Number, or patient identification number.''

SAFEGUARDS:

Delete entry and replace with ''Physical access to the information technology (IT) system location is restricted by visitor escort, access rosters, and photo identification. Adequate locks are on doors and server components are secured in a locked computer room with limited access. Each end user device is protected within a locked storage container, room, or building outside of normal business hours. All visitors and other persons that require access to facilities that house servers and other network devices supporting the IT system that do not have authorization for access are escorted by appropriately screened/cleared personnel at all times.

Access to the IT system is role-based and a valid user account is required. The system is Public Key Infrastructure-enforced with two-factor authentication and can be accessed by use of Common Access Card and personal identification number. Authorized personnel must have appropriate Information Assurance training, HIPAA training, and Privacy Act training.

Paper records are protected by the security and policies in place at the locations where they are held. All locations are within or under contract with the MHS, and require personnel to undergo appropriate training.''

RETENTION AND DISPOSAL:

Delete entry and replace with ''Close out at end of the calendar year in which received. Destroy 10 year(s) after cut off.''

SYSTEM MANAGER(S) AND ADDRESS:

Delete entry and replace with ''Program Manager, DHA Solutions Delivery Division, Clinical Support, Fort Sam Houston, San Antonio, TX 78234–2639.''

NOTIFICATION PROCEDURE:

Delete entry and replace with ''Individuals seeking to determine whether information about themselves is contained in this system of records should address written inquiries to the Chief, Freedom of Information Act (FOIA) Service Center, Defense Health Agency Privacy and Civil Liberties Office, 7700 Arlington Boulevard, Suite 5101, Falls Church, VA 22042–5101.

Requests should contain the name and number of this system of records notice, the individual's full name, current address, home or cell phone telephone number, SSN or DoD ID Number, and signature.

In addition, the requester must provide a notarized statement or an unsworn declaration made in accordance with 28 U.S.C. 1746, in the following format:

If executed outside the United States: 'I declare (or certify, verify, or state) under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on (date). (Signature).'

If executed within the United States, its territories, possessions, or commonwealths: 'I declare (or certify, verify, or state) under penalty of perjury that the foregoing is true and correct. Executed on (date). (Signature).'

If requesting information about a minor or legally incompetent person, the request must be made by the custodial parent, legal guardian, or person with legal authority to make decisions on behalf of the individual. Written proof of that status may be required before the existence of any information will be confirmed.''

RECORD ACCESS PROCEDURES:

Delete entry and replace with ''Individuals seeking access to records about themselves contained in this system of records should address written inquiries to the Chief, FOIA Service Center, Defense Health Agency Privacy and Civil Liberties Office, 7700 Arlington Boulevard, Suite 5101, Falls Church, VA 22042–5101.

Requests should contain the name and number of this system of records notice, the individual's full name, current address, home or cell phone telephone number, SSN or DoD ID Number, and signature.

In addition, the requester must provide a notarized statement or an unsworn declaration made in accordance with 28 U.S.C. 1746, in the following format:

If executed outside the United States: 'I declare (or certify, verify, or state) under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on (date). (Signature).'

If executed within the United States, its territories, possessions, or commonwealths: 'I declare (or certify, verify, or state) under penalty of perjury that the foregoing is true and correct. Executed on (date). (Signature).'

If requesting information about a minor or legally incompetent person, the request must be made by the custodial parent, legal guardian or person with legal authority to make decisions on behalf of the individual. Written proof of that status may be required before any records will be provided."

CONTESTING RECORD PROCEDURES:

Delete entry and replace with "The Office of the Secretary of Defense (OSD) rules for accessing records, for contesting contents and appealing initial agency determinations are published in OSD Administrative Instruction 81, 32 CFR part 311, or may be obtained from the system manager."

RECORD SOURCE CATEGORIES:

Delete entry and replace with "The Composite Health Care System (CHCS) and the individual."

* * * * *

[FR Doc. 2016–16726 Filed 7–14–16; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF EDUCATION

[Docket No. ED–2016–ICCD–0079]

Agency Information Collection Activities; Comment Request; Cash Management Contract URL Collection

AGENCY: Federal Student Aid (FSA), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 3501 *et seq.*), ED is proposing a new information collection.

DATES: Interested persons are invited to submit comments on or before September 13, 2016.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use *http://www.regulations.gov* by searching the Docket ID number ED–2016–ICCD–0079. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Information Collection Clearance Division, U.S. Department of Education, 400 Maryland Avenue SW., LBJ, Room 2E–347, Washington, DC 20202–4537.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Beth Grebeldinger, 202–377–4018.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Cash Management Contract URL Collection.

OMB Control Number: 1845–NEW.

Type of Review: A new information collection.

Respondents/Affected Public: State, Local, and Tribal Governments; Private Sector.

Total Estimated Number of Annual Responses: 914.

Total Estimated Number of Annual Burden Hours: 73.

Abstract: The Department of Education (the Department) is seeking a new OMB control number for the collection of URLs hosting institutional contracts and contract data relating to campus banking agreements. This is a new requirement of the final Program Integrity and Improvement regulations published on October 30, 2015. When the Department added the requirement for institutions to post campus banking agreement contracts and contract data to their Web sites, consumer advocates requested that a central repository for these Web addresses be made publicly available for research and comparison purposes. This database will allow interested parties, such as students, families, press, institutions, and researchers to easily access and compare banking agreements available at different institutions.

Dated: July 12, 2016.

Kate Mullan,

Acting Director, Information Collection Clearance Division, Office of the Chief Privacy Officer, Office of Management.

[FR Doc. 2016–16737 Filed 7–14–16; 8:45 am]

BILLING CODE 4000–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9949–10–ORD]

EPA Board of Scientific Counselors; Charter Renewal

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of charter renewal.

SUMMARY: Notice is hereby given that the Environmental Protection Agency (EPA) has determined that, in accordance with the provisions of the Federal Advisory Committee Act (FACA), 5 U.S.C. App. 2, the EPA Board of Scientific Counselors Advisory Board (BOSC) is a necessary committee that is in the public interest. Accordingly, the BOSC will be renewed for an additional two-year period. The purpose of BOSC is to provide advice and recommendations to the Administrator regarding science and engineering research, programs and plans, laboratories, and research management practices. Inquiries may be directed to Tom Tracy, U.S. EPA, (Mail Code 8104R), 1200 Pennsylvania Avenue NW., Washington, DC 20460, telephone (202) 564–6518, or *tracy.tom@epa.gov.*

Dated: June 27, 2016.

Thomas Burke,

Deputy Assistant Administrator, Office of Research and Development.

[FR Doc. 2016–16790 Filed 7–14–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2015–0762; FRL–9947–90]

Registration Review; Conventional, Biopesticide and Antimicrobial Dockets Opened for Review and Comment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: With this document, EPA is opening the public comment period for several registration review cases. Registration review is EPA's periodic review of pesticide registrations to ensure that each pesticide continues to satisfy the statutory standard for registration, that is, the pesticide can perform its intended function without unreasonable adverse effects on human health or the environment. Registration review dockets contain information that will assist the public in understanding the types of information and issues that the Agency may consider during the course of registration reviews. Through this program, EPA is ensuring that each pesticide's registration is based on current scientific and other knowledge, including its effects on human health and the environment. For dicamba, EPA is seeking comment on the preliminary work plan, the ecological problem formulation, and the human health draft risk assessment. This document also announces the Agency's intent not to open a registration review docket for alachlor (case #: 0063) and propachlor (case #: 0177). These pesticides do not currently have any actively registered pesticide products and are not, therefore, scheduled for review under the registration review program.

DATES: Comments must be received on or before September 13, 2016.

ADDRESSES: Submit your comments identified by the docket identification (ID) number for the specific pesticide of interest provided in the table in Unit III.A., by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: *For pesticide specific information contact:* The person identified as a contact in the table in Unit III.A. Also include the docket ID number listed in the table in Unit III.A. for the pesticide of interest.

For general information contact: Richard Dumas, Pesticide Re-Evaluation Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 308–8015; fax number: (703) 308–8090; email address: *dumas.richard@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This action is directed to the public in general, and may be of interest to a wide range of stakeholders including environmental, human health, farmworker, and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides. Since others also may be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action.

B. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through *regulations.gov* or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at *http://www.epa.gov/dockets/comments.html.*

3. *Environmental justice.* EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of any group, including minority and/or low income populations, in the development, implementation, and enforcement of environmental laws, regulations, and policies. To help address potential environmental justice issues, the Agency seeks information on any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have atypical or disproportionately high and adverse human health impacts or environmental effects from exposure to the pesticides discussed in this document, compared to the general population.

II. Authority

EPA is initiating its reviews of the pesticides identified in this document pursuant to section 3(g) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136a(g)) and the Procedural Regulations for Registration Review at 40 CFR part 155, subpart C. Section 3(g) of FIFRA provides, among other things, that the registrations of pesticides are to be reviewed every 15 years. Under FIFRA, a pesticide product may be registered or remain registered only if it meets the statutory standard for registration given in FIFRA section 3(c)(5) (7 U.S.C. 136a(c)(5)). When used in accordance with widespread and commonly recognized practice, the pesticide product must perform its intended function without unreasonable adverse effects on the environment; that is, without any unreasonable risk to man or the environment, or a human dietary risk from residues that result from the use of a pesticide in or on food.

III. Registration Reviews

A. What action is the agency taking?

As directed by FIFRA section 3(g), EPA is reviewing the pesticide registrations identified in the table in this unit to assure that they continue to satisfy the FIFRA standard for registration—that is, they can still be used without unreasonable adverse effects on human health or the environment. A pesticide's registration review begins when the Agency establishes a docket for the pesticide's registration review case and opens the docket for public review and comment. At present, EPA is opening registration review dockets for the cases identified in the following table.

TABLE 1—REGISTRATION REVIEW DOCKETS OPENING

Registration review case name and No.	Docket ID No.	Contact
Acetochlor, 7230	EPA–HQ–OPP–2016–0298	Linsey Walsh, *walsh.linsey@epa.gov,* (703) 347–8030.
Bromethalin, 2765	EPA–HQ–OPP–2016–0077	Christina Motilall, *motilall.christina@epa.gov,* (703) 603–0522.
Chlorflurenol Methyl Ester, 2095	EPA–HQ–OPP–2016–0037	Wilhelmena Livingston, *livingston.wilhelmena@epa.gov,* (703) 308–8025.
Cholecalciferol, 7600	EPA–HQ–OPP–2016–0139	James Parker, *parker.james@epa.gov,* (703) 306–0469.
Corn Glutens, 6040	EPA–HQ–OPP–2016–0253	Russell Jones, *jones.russell@epa.gov,* (703) 308–5071; Judy Facey, *facey.judy@epa.gov,* (703) 305–5450.
Dicamba, 0065	EPA–HQ–OPP–2016–0223	Marquea D. King, *king.marquea@epa.gov,* (703) 305–7432.
Dimethenamid and Dimethenamid-P, 7223	EPA–HQ–OPP–2015–0803	Maria Piansay, *piansay.maria@epa.gov,* (703) 308–8063; Jordan Page, *page.jordan@epa.gov.* (703) 347–0467.
Florasulam, 7274	EPA–HQ–OPP–2015–0548	Moana Appleyard, *appleyard.moana@epa.gov,* (703) 308–8175.
Glutaraldehyde, 2315	EPA–HQ–OPP–2015–0738	Stephen Savage, *savage.stephen@epa.gov,* (703) 347–0345.
Predator Urines: Coyote Urine and Fox Urine, 6202.	EPA–HQ–OPP–2016–0086	Menyon Adams, *adams.menyon@epa.gov,* (703) 347–8496; Judy Facey, *facey.judy@epa.gov,* (703) 305–5450.
Reynoutria sachalinensis (Milsana), 6030	EPA–HQ–OPP–2016–0232	Chris Pfeifer, *pfeifer.chris@epa.gov,* (703) 308–0031; Judy Facey, *facey.judy@epa.gov,* (703) 305–5450.
Siduron, 3130	EPA–HQ–OPP–2015–0857	Leigh Rimmer, *rimmer.leigh@epa.gov,* (703) 347–0553.
Triforine, 2720	EPA–HQ–OPP–2015–0853	Susan Bartow, *bartow.susan@epa.gov,* (703) 603–0065.
Verticillium isolate WCS850, 6508	EPA–HQ–OPP–2016–0306	Michael Glikes, *glikes.michael@epa.gov,* (703) 305–6231.
Zinc Phosphide, 0026	EPA–HQ–OPP–2016–0140	James Parker, *parker.james@epa.gov,* (703) 306–0469.

For dicamba (case #: 0065), EPA is seeking comment on the preliminary work plan, the ecological problem formulation, and the human health draft risk assessment. EPA is also announcing that it will not be opening a docket for alachlor (case #: 0063) and propachlor (case #: 0177) because these pesticides are not included in any products actively registered under FIFRA section 3 or 24(c). The Agency will take separate action to propose revocation of any affected tolerances that are not supported for import purposes only.

B. Docket Content

1. *Review dockets.* The registration review dockets contain information that the Agency may consider in the course of the registration review. The Agency may include information from its files including, but not limited to, the following information:

- An overview of the registration review case status.
- A list of current product registrations and registrants.
- **Federal Register** notices regarding any pending registration actions.
- **Federal Register** notices regarding current or pending tolerances.
- Risk assessments.
- Bibliographies concerning current registrations.
- Summaries of incident data.
- Any other pertinent data or information.

Each docket contains a document summarizing what the Agency currently knows about the pesticide case and a preliminary work plan for anticipated data and assessment needs. Additional documents provide more detailed information. During this public comment period, the Agency is asking that interested persons identify any additional information they believe the Agency should consider during the registration reviews of these pesticides. The Agency identifies in each docket the areas where public comment is specifically requested, though comment in any area is welcome.

2. *Other related information.* More information on these cases, including the active ingredients for each case, may be located in the registration review schedule on the Agency's Web site at *https://www.epa.gov/pesticide-reevaluation/registration-review-schedules.* Information on the Agency's registration review program and its implementing regulation may be seen at *http://www.epa.gov/pesticide-reevaluation/registration-review-process.*

3. *Information submission requirements.* Anyone may submit data or information in response to this document. To be considered during a pesticide's registration review, the submitted data or information must meet the following requirements:

- To ensure that EPA will consider data or information submitted, interested persons must submit the data or information during the comment period. The Agency may, at its discretion, consider data or information submitted at a later date.
- The data or information submitted must be presented in a legible and useable form. For example, an English

translation must accompany any material that is not in English and a written transcript must accompany any information submitted as an audiographic or videographic record. Written material may be submitted in paper or electronic form.

- Submitters must clearly identify the source of any submitted data or information.
- Submitters may request the Agency to reconsider data or information that the Agency rejected in a previous review. However, submitters must explain why they believe the Agency should reconsider the data or information in the pesticide's registration review.

As provided in 40 CFR 155.58, the registration review docket for each pesticide case will remain publicly accessible through the duration of the registration review process; that is, until all actions required in the final decision on the registration review case have been completed.

Authority: 7 U.S.C. 136 *et seq.*

Dated: July 6, 2016.

Michael Goodis,

Acting Director, Pesticide Re-evaluation Division, Office of Pesticide Programs.

[FR Doc. 2016–16788 Filed 7–14–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2015–0317; FRL–9948–05]

Amendments To Terminate Uses for Certain Pesticide Registrations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces EPA's final order for the amendments to terminate uses, voluntarily requested by the registrants and accepted by the Agency, of the products listed in Table 1, pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). This cancellation order follows a June 10, 2015 **Federal Register** Notice of Receipt of Requests from the registrants listed in Table 2 to amend uses of these product registrations. These are not the last products containing these pesticides registered for use in the United States. In the June 10, 2015 notice, EPA indicated that it would issue an order implementing the amendments to terminate uses, unless the Agency received substantive comments within the 30 and 180 day comment periods that would merit its further review of these requests, or unless the registrants withdrew their requests. The Agency did not receive any comments on the notice. Further, the registrants did not withdraw their requests. Accordingly, EPA hereby issues in this notice a cancellation order granting the requested amendments to terminate uses. Any distribution, sale, or use of the products subject to this cancellation order is permitted only in accordance with the terms of this order, including any existing stocks provisions.

DATES: The cancellations are effective July 15, 2016.

FOR FURTHER INFORMATION CONTACT: Ricardo Jones, Pesticide Re-Evaluation Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; main telephone number: (703) 347–0493; email address: *jones.ricardo@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This action is directed to the public in general, and may be of interest to a wide range of stakeholders including environmental, human health, and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides. Since others also may be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action.

B. How can I get copies of this document and other related information?

The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2015–0317, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

II. What action is the agency taking?

This notice announces the amendments to terminate uses, as requested by registrants of products registered under FIFRA section 3 (7 U.S.C. 136a). These registrations are listed in sequence by registration number in Table 1 of this unit.

TABLE 1—PRODUCT REGISTRATION AMENDMENTS TO TERMINATE USES

EPA registration No.	Product name	Chemical name	Uses terminated
1021–2782	Clothianidin Technical	Clothianidin	Fruiting Vegetables Crop Grouping (CG8) and Low-Growing Berry except Strawberry (CG13–07H) and retain the existing tolerances.
59639–150	V–10170 2.13SC Insecticide	Clothianidin	Fruiting Vegetables Crop Grouping (CG8) and Low-Growing Berry except Strawberry (CG13–07H) and retain the existing tolerances.
59639–152	Arena 50 WDG Insecticide	Clothianidin	Fruiting Vegetables Crop Grouping (CG8) and Low-Growing Berry except Strawberry (CG13–07H) and retain the existing tolerances.
59639–173	Clothianidin Technical Insecticide.	Clothianidin	Fruiting Vegetables Crop Grouping (CG8) and Low-Growing Berry except Strawberry (CG13–07H) and retain the existing tolerances.

TABLE 1—PRODUCT REGISTRATION AMENDMENTS TO TERMINATE USES—Continued

EPA registration No.	Product name	Chemical name	Uses terminated
90963–1	Nipacide MX	Chloroxylenol	As a preservative for paints, plastics and plastic coatings, thickeners & adhesives/binders. As a disinfectant, sanitizer, deodorizer or antimicrobial agent for application to hard, non-porous surfaces in residential, health-care, institutional, food-processing and industrial facilities including animal housing facilities, veterinary clinics, farms, live-stock, swine and poultry houses. As a biocide in oil and gas exploration including enhanced recovery systems, flood water, fracturing fluids and gels, injection waters, pipelines, holding pond water, disposal well water, tubing, pressure vessels and storage tanks. As a biocide in industrial process water systems.
90963–2	Nipacide CMX	Chloroxylenol	As a preservative for paints, plastics and plastic coatings, thickeners & adhesives/binders. As a disinfectant, sanitizer, deodorizer or antimicrobial agent for application to hard, non-porous surfaces in residential, health-care, institutional, food-processing and industrial facilities including animal housing facilities, veterinary clinics, farms, live-stock, swine and poultry houses. As a biocide in oil and gas exploration including enhanced recovery systems, flood water, fracturing fluids and gels, injection waters, pipelines, holding pond water, disposal well water, tubing, pressure vessels and storage tanks. As a biocide in industrial process water systems.

Table 2 of this unit includes the names and addresses of record for all registrants of the products in Table 1 of this unit, in sequence by EPA company number.

TABLE 2—REGISTRANTS OF AMENDED PRODUCTS

EPA company No.	Company name and address
1021	McLaughlin Gormley King Company, 8810 Tenth Avenue North, Minneapolis, MN 55427–4319.
59639	Valent U.S.A. Corporation, 1600 Riviera Avenue, Suite 200, Walnut Creek, CA 94596.
90963	Ortho-Clinical Diagnostics, Inc., Agent Name: Lewis & Harrison, LLC, 122 C Street NW., Suite 505, Washington, DC 20001.

III. Summary of Public Comments Received and Agency Response to Comments

During the public comment period provided, EPA received no comments in response to the June 10, 2015 **Federal Register** notice announcing the Agency's receipt of the requests for amendments to terminate uses of products listed in Table 1 of Unit II.

IV. Cancellation Order

Pursuant to FIFRA section 6(f) (7 U.S.C. 136d(f)), EPA hereby approves the requested amendments to terminate uses of clothianidin and chloroxylenol registrations identified in Table 1 of Unit II. Accordingly, the Agency orders that the product registrations identified in Table 1 of Unit II. are hereby amended to terminate the affected uses. The effective date of the amendments to terminate affected uses is July 15, 2016. Any distribution, sale, or use of existing stocks of the products identified in Table 1 of Unit II. in a manner inconsistent with any of the provisions for disposition of existing stocks set forth in Unit VI. will be considered a violation of FIFRA.

V. What is the agency's authority for taking this action?

Section 6(f)(1) of FIFRA (7 U.S.C. 136d(f)(1)) provides that a registrant of a pesticide product may at any time request that any of its pesticide registrations be canceled or amended to terminate one or more uses. FIFRA further provides that, before acting on the request, EPA must publish a notice of receipt of any such request in the **Federal Register**. Thereafter, following the public comment period, the EPA Administrator may approve such a request. The notice of receipt for this action was published for comment in the **Federal Register** of June 10, 2015, (80 FR 32947) (FRL–9928–01). The comment period for chloroxylenol closed on July 10, 2015, and the comment period for clothianidin closed on January 6, 2016.

VI. Provisions for Disposition of Existing Stocks

EPA's existing stocks policy published in the **Federal Register** of June 26, 1991 (56 FR 29362) provides that: "If a registrant requests to voluntarily cancel a registration where the Agency has identified no particular risk concerns, the registrant has complied with all applicable conditions of reregistration, conditional registration, and data call ins, and the registration is not subject to a Registration Standard, Label Improvement Program, or reregistration decision, the Agency will generally permit a registrant to sell or distribute existing stocks for 1 year after the cancellation request was received. Persons other than registrants will generally be allowed to sell, distribute, or use existing stocks until such stocks are exhausted."

Existing stocks are those stocks of registered pesticide products which are currently in the United States and which were packaged, labeled, and released for shipment prior to the effective date of the cancellation action. The effective date of this cancellation is July 15, 2016. The cancellation order that is the subject of this notice includes the following existing stock provisions:

The registrant may sell and distribute existing stocks of products listed in Table 1 of Unit II. until July 17, 2017. Persons other than the registrant may sell and distribute existing stocks of products listed in Table 1 of Unit II. until exhausted. Use of the products listed in Table 1 of Unit II. may continue until existing stocks are exhausted, provided that such use is consistent with the terms of the previously approved labeling on, or that accompanied, the canceled products.

Authority: 7 U.S.C. 136 *et seq.*

Dated: July 7, 2016.

Michael Goodis,

Acting Director, Pesticide Re-Evaluation Division, Office of Pesticide Programs.

[FR Doc. 2016–16793 Filed 7–14–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–9028–1]

Environmental Impact Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information (202) 564–7146 or *http://www2.epa.gov/nepa.*

Weekly receipt of Environmental Impact Statements (EISs) Filed 07/05/2016 Through 07/08/2016

Pursuant to 40 CFR 1506.9.

Notice

Section 309(a) of the Clean Air Act requires that EPA make public its comments on EISs issued by other Federal agencies. EPA's comment letters on EISs are available at: *http://www.epa.gov/compliance/nepa/eisdata.html.*

EIS No. 20160153, Final, Caltrans, CA, High Desert Corridor, Review Period Ends: 08/15/2016, Contact: Ron Kosinski 213–897–0703

EIS No. 20160154, Final, NPS, MA, Herring River Restoration Project, Review Period Ends: 08/15/2016, Contact: Mark Husbands 303–987–6965

EIS No. 20160155, Final, FTA, MN, Bottineau Light Rail Transit Metro Blue Line Extension, Review Period Ends: 08/15/2016, Contact: Maya Sarna 202–366–5811

EIS No. 20160156, Draft, FRA, TX, Texas-Oklahoma Passenger Rail Study Service-Level, Comment Period Ends: 08/29/2016, Contact: Melissa Hatcher 202–493–6075

EIS No. 20160157, Final, USN, WA, Land-Water Interface and Service Pier Extension at Naval Base Kitsap Bangor, Review Period Ends: 08/15/2016, Contact: Robin Senner 360–396–0029

EIS No. 20160158, Draft, MARAD, USCG, LA, Port Delfin LNG Project Deepwater Port Application, Comment Period Ends: 08/29/2016, Contact: Roddy C. Bachman 202–372–1451

The U.S. Coast Guard and the Maritime Administration are joint lead agencies for the above project.

EIS No. 20160159, Draft, FERC, OH, NEXUS Gas Transmission Project and Texas Eastern Appalachian Lease Project, Comment Period Ends: 08/29/2016, Contact: Joanne Wachholder 202–502–8056

EIS No. 20160160, Final, BR, CA, Mendota Pool Bypass and Reach 2B Improvements Project, Review Period Ends: 08/15/2016, Contact: Becky Victorine 916–978–4624

EIS No. 20160161, Final, USACE, WA, Puget Sound Nearshore Ecosystem Restoration, Review Period Ends: 08/15/2016, Contact: Nancy C. Gleason 206–764–6577

EIS No. 20160162, Final, USFS, MT, Telegraph Vegetation Project, Review Period Ends: 08/15/2016, Contact: Sharon Scott 406–495–3943

EIS No. 20160163, Final, DOE, LA, ADOPTION—Lake Charles Liquefaction Project, Contact: John Anderson 202–586–0521

The U.S. Department of Energy (DOE) has adopted the Federal Energy Regulatory Commission's Final EIS #20150233 filed 08/14/2015 with EPA. DOE was a cooperating agency, therefore recirculation of the document is not necessary under Section 1506.3(b) of the CEQ Regulations.

Amended Notices

EIS No. 20160085, Draft, USFWS, WY, Eagle Take Permits for the Chokecherry and Sierra Madre Phase I Wind Energy Project, Comment Period Ends: 07/29/2016, Contact: Louise Galiher 303–236–8677

Revision to FR Notice Published 04/29/2016; The U.S. Fish and Wildlife Service has reopened the comment period to end 07/29/2016

EIS No. 20160115, Draft, DOD, Other, Continental United States (CONUS) Interceptor Site, Comment Period Ends: 08/17/2016, Contact: Christopher Johnson 571–231–8212

Revision to FR Notice Published 06/03/2016; Extending Comment Period from 07/18/2016 to 08/17/2016

Dated: July 12, 2016.

Karin Leff,

Acting Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 2016–16800 Filed 7–14–16; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

[IB Docket No. 16–185; DA 16–630 and DA 16–780]

Announcement of Rechartering and First Meeting of the World Radiocommunication Conference Advisory Committee

AGENCY: Federal Communications Commission.

ACTION: Notice.

SUMMARY: In accordance with the Federal Advisory Committee Act, the Federal Communications Commission (FCC) announces that the charter for the World Radiocommunication Conference Advisory Committee (WRCAC) has been renewed by the General Services Administration (GSA) for a two-year period. The WRCAC is a federal advisory committee under the Federal Advisory Committee Act. This notice advises interested persons that the initial meeting of the WRCAC will be held to begin preparations for the 2019 World Radiocommunication Conference.

DATES: Tuesday, August 2, 2016; 11:00 a.m.

ADDRESSES: Federal Communications Commission, 445 12th Street SW., Room TW–C305, Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Dante Ibarra, Designated Federal Official, World Radiocommunication Conference Advisory Committee, FCC International Bureau, Global Strategy and Negotiation Division, at (202) 418–0610. Email: *Dante.Ibarra@fcc.gov.*

SUPPLEMENTARY INFORMATION: In accordance with the Federal Advisory Committee Act, Public Law 92–463, as amended, this notice advises interested persons that the GSA has renewed the charter of the WRCAC through April 8, 2018. Its scope of activities is to address issues contained in the agenda for the International Telecommunication Union (ITU) World Radiocommunication Conferences. The WRCAC will continue to provide to the FCC advice, data, and technical analyses, and will formulate recommendations relating to the preparation of U.S. proposals and positions for ITU World Radiocommunication Conferences, specifically the World Radiocommunication Conference that has been preliminarily scheduled for the year 2019 (WRC–19).

This notice advises interested persons of the first meeting of the WRCAC. Additional information regarding the WRC–19 and the WRCAC is available on the WRCAC's Web site, *https://www.fcc.gov/wrc-19.* The meeting is open to the public.

Open captioning will be provided for this event. Other reasonable accommodations for people with disabilities are available upon request. Requests for such accommodations should be submitted via email to *fcc504@fcc.gov* or by calling the Consumer & Governmental Affairs Bureau at (202) 418–0530 (voice), (202) 418–0432 (TTY). Such requests should include a detailed description of the accommodation needed. In addition, please include a way for the FCC to contact the requester if more information is needed to fill the request. Please allow at least five days' advance notice; last minute requests will be accepted, but may not be possible to accommodate.

The proposed agenda for the first meeting is as follows:

Agenda

First Meeting of the World Radiocommunication Conference Advisory Committee

Federal Communications Commission, 445 12th Street SW., Room TW–C305, Washington, DC 20554, August 2, 2016; 11:00 a.m.

1. Opening Remarks
2. Approval of Agenda
3. Advisory Committee Structure
4. WRC–19 Preparatory Process Timeline
5. Other Business

Federal Communications Commission.

Denise Coca,

Chief, Telecommunications and Analysis Division, International Bureau.

[FR Doc. 2016–16716 Filed 7–14–16; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The applications will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than August 12, 2016.

A. Federal Reserve Bank of New York (Ivan Hurwitz, Vice President) 33 Liberty Street, New York, New York 10045–0001. Comments can also be sent electronically to *Comments.applications@ny.frb.org:*

1. *CheckSpring Community Corporation NY,* Bronx, New York; to become a bank holding company by acquiring 100 percent of the shares of Spring Bank, Bronx, New York.

Board of Governors of the Federal Reserve System, July 12, 2016.

Michele Taylor Fennell,

Assistant Secretary of the Board.

[FR Doc. 2016–16748 Filed 7–14–16; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than August 1, 2016.

A. Federal Reserve Bank of Minneapolis (Jacquelyn K. Brunmeier, Assistant Vice President) 90 Hennepin Avenue, Minneapolis, Minnesota 55480–0291:

1. *Jeffrey A. Fisher,* Bigfork, Minnesota; to retain 25 percent or more of the shares of Bigfork Bancshares, Inc., Bigfork, Minnesota, and thereby indirectly retain control of First State Bank of Bigfork, Bigfork, Minnesota.

Board of Governors of the Federal Reserve System, July 11, 2016.

Michele Taylor Fennell,

Assistant Secretary of the Board.

[FR Doc. 2016–16696 Filed 7–14–16; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL TRADE COMMISSION

[File No. 152 3034]

Warner Bros. Home Entertainment Inc.; Analysis of Proposed Consent Order to Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed Consent Agreement.

SUMMARY: The consent agreement in this matter settles alleged violations of federal law prohibiting unfair or deceptive acts or practices. The attached Analysis to Aid Public Comment describes both the allegations in the draft complaint and the terms of the consent order—embodied in the consent agreement—that would settle these allegations.

DATES: Comments must be received on or before August 10, 2016.

ADDRESSES: Interested parties may file a comment at *https://ftcpublic.commentworks.com/ftc/warnerbrothersconsent* online or on paper, by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Write "In the Matter of Warner Bros. Home Entertainment Inc., File No. 152 3034—Consent Agreement" on your comment and file your comment online at *https://ftcpublic.commentworks.com/ftc/warnerbrothersconsent* by following the instructions on the web-based form. If you prefer to file your comment on paper, write "In the Matter of Warner Bros. Home Entertainment Inc., File No. 152 3034—Consent Agreement" on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW., Suite CC–5610 (Annex D), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW., 5th Floor, Suite 5610 (Annex D), Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Linda K. Badger, (415–848–5151), FTC Western Region, 901 Market Street, Suite 570, San Francisco, CA 94103.

SUPPLEMENTARY INFORMATION: Pursuant to Section 6(f) of the Federal Trade Commission Act, 15 U.S.C. 46(f), and FTC Rule 2.34, 16 CFR 2.34, notice is hereby given that the above-captioned consent agreement containing consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of thirty (30) days. The following Analysis to Aid Public Comment describes the terms of the consent agreement, and the allegations in the complaint. An electronic copy of the full text of the consent agreement package can be obtained from the FTC Home Page (for July 11, 2016), on the World Wide Web at: *http://www.ftc.gov/os/actions.shtm.*

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before August 10, 2016. Write "In the Matter of Warner Bros. Home Entertainment Inc., File No. 152 3034—Consent Agreement" on your comment. Your comment—including your name and your state—will be placed on the public record of this proceeding, including, to the extent practicable, on the public Commission Web site, at *http://www.ftc.gov/os/publiccomments.shtm.* As a matter of discretion, the Commission tries to remove individuals' home contact information from comments before placing them on the Commission Web site.

Because your comment will be made public, you are solely responsible for making sure that your comment does not include any sensitive personal information, like anyone's Social Security number, date of birth, driver's license number or other state identification number or foreign country equivalent, passport number, financial account number, or credit or debit card number. You are also solely responsible for making sure that your comment does not include any sensitive health information, like medical records or other individually identifiable health information. In addition, do not include any "[t]rade secret or any commercial or financial information which . . . is privileged or confidential," as discussed in Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2). In particular, do not include competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

If you want the Commission to give your comment confidential treatment, you must file it in paper form, with a request for confidential treatment, and you have to follow the procedure explained in FTC Rule 4.9(c), 16 CFR 4.9(c).[1] Your comment will be kept confidential only if the FTC General Counsel, in his or her sole discretion, grants your request in accordance with the law and the public interest.

Postal mail addressed to the Commission is subject to delay due to heightened security screening. As a result, we encourage you to submit your comments online. To make sure that the Commission considers your online comment, you must file it at *https://ftcpublic.commentworks.com/ftc/warnerbrothersconsent* by following the instructions on the web-based form. If this Notice appears at *http://www.regulations.gov/#!home,* you also may file a comment through that Web site.

If you file your comment on paper, write "In the Matter of Warner Bros. Home Entertainment Inc., File No. 152 3034—Consent Agreement" on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW., Suite CC–5610 (Annex D), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW., 5th Floor, Suite 5610 (Annex D), Washington, DC 20024. If possible, submit your paper comment to the Commission by courier or overnight service.

Visit the Commission Web site at *http://www.ftc.gov* to read this Notice and the news release describing it. The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before August 10, 2016. You can find more information, including routine uses permitted by the Privacy Act, in the Commission's privacy policy, at *http://www.ftc.gov/ftc/privacy.htm.*

Analysis of Proposed Consent Order To Aid Public Comment

The Federal Trade Commission ("FTC" or "Commission") has accepted, subject to final approval, an agreement containing consent order from Warner Bros. Home Entertainment Inc. ("Warner Bros." or "respondent"). The proposed consent order ("proposed order") has been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will again review the agreement and the comments received, and will decide whether it should withdraw from the agreement and take appropriate action or make final the agreement's proposed order.

This matter involves respondent's use of social media influencers to advertise the video game, *Middle Earth: Shadow of Mordor* ("*Shadow of Mordor*"). According to the Commission's complaint, Warner Bros., through its ad agency, Plaid Social Labs, LLC, hired individuals who had earned reputations as video game enthusiasts on YouTube ("YouTube influencers") to post positive videos promoting *Shadow of Mordor* on YouTube. The Commission's complaint alleges that these YouTube influencers were given free access to a pre-release version of *Shadow of Mordor* and cash payments often ranging from hundreds of dollars to tens of thousands of dollars, if the videos they created about *Shadow of Mordor* met certain requirements defined by Warner Bros. Among other things, Warner Bros. required influencer videos to promote a positive sentiment about the game, and not to disclose any bugs or glitches that the game might have. Consequently, these videos were sponsored advertisements, and did not necessarily reflect the independent experiences of the individual YouTube influencers.

The complaint also alleges that while Warner Bros. instructed the YouTube influencers to provide a disclosure that their videos had been sponsored, it specified that the disclosure be written, and placed in the description box appearing below the YouTube videos. Warner Bros. did not require the YouTube influencers to place a sponsorship disclosure clearly and conspicuously in the video itself. Nor did Warner Bros. require that the YouTube influencers be instructed to place the sponsorship disclosure "above the fold" in the description box, or visible without consumers having to scroll down or click on a link, as it had for other promotional information about *Shadow of Mordor.* (*See, e.g.,* Exhibit A–1) As a result, most YouTube influencers did not include any sponsorship disclosures in their videos, and only placed their sponsorship disclosures "below the fold" in the description box below the video. Therefore, consumers had to click on a "Show More" button in the description box and potentially scroll down before they could see the sponsorship disclosure. As a result, consumers who watched these YouTube videos were unlikely to learn that the videos were paid promotions for Warner Bros.

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[1] In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. *See* FTC Rule 4.9(c), 16 CFR 4.9(c).

The Commission's complaint further alleges that when YouTube influencers posted their *Shadow of Mordor* videos for viewing on Facebook or Twitter, consumers were even less likely to see these sponsorship disclosures because such posts did not include the "Show More" button. In addition, the complaint states that on at least two occasions, the influencers disclosed only that they had been given early access to the game, and did not adequately disclose that they had also been paid to post the video.

According to the complaint, in numerous instances, YouTube influencers did not disclose or adequately disclose that Warner Bros., through Plaid Social, offered compensation to the influencers in exchange for creating and uploading gameplay videos as part of a *Shadow of Mordor* advertising campaign. The Commission's complaint alleges that these videos were false and misleading because they did not reflect the independent opinions or experiences of impartial video game enthusiasts. The complaint further alleges that the videos were deceptive because they failed to disclose or disclose adequately that the influencers who posted the videos were compensated in connection with their endorsements.

The proposed order includes injunctive relief to address these alleged violations and requires Warner Bros. to follow certain monitoring and compliance procedures related to its use of influencer campaigns.

Part I of the proposed order prohibits Warner Bros., in connection with the advertising of any home entertainment product or service, from misrepresenting in any influencer campaign that an influencer or endorser of such product or service is an independent user or ordinary consumer of the product or service.

Part II of the proposed order requires Warner Bros., in connection with the advertising of any home entertainment product or service by means of an endorsement, in any influencer campaign, to disclose clearly and conspicuously a material connection, if one exists, between the influencer or endorser and Warner Bros.

Part III of the proposed order sets out certain monitoring and compliance obligations to ensure that Warner Bros., or any entity it engages to conduct an influencer campaign, comply with Parts I and II of the proposed order. These obligations include: Obtaining signed acknowledgements from such influencers that they will disclose their material connection to Warner Bros.; monitoring the influencers' representations and disclosures; maintaining records of monitoring efforts; and, under certain circumstances, terminating and ceasing payment to influencers who misrepresent their independence, or fail to properly disclose any material connection to Warner Bros. Part III specifically provides that if Warner Bros. engages an entity to conduct an influencer campaign, Warner Bros. must take steps to ensure that the entity complies with this Part, and to monitor its compliance. If the entity fails to comply with this Part, Warner Bros. must cease payment to the entity until it cures any noncompliance. Furthermore, Warner Bros. is required to disqualify the entity from conducting future influencer campaigns upon a repeat incident, unless it reasonably concludes that the entity's failure to comply was inadvertent.

Part IV of the proposed order contains recordkeeping requirements for relevant documents.

Parts V through VII of the proposed order require the company to: Provide copies of the order to certain personnel having responsibilities with respect to the subject matter of the order; notify the Commission of changes in corporate structure that might affect compliance obligations under the order; and file compliance reports with the Commission.

Part VIII of the proposed order provides that the order will terminate after twenty (20) years, with certain exceptions.

The purpose of this analysis is to facilitate public comment on the proposed order, and it is not intended to constitute an official interpretation of the complaint or proposed order, or to modify the proposed order's terms in any way.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 2016–16729 Filed 7–14–16; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–339 and CMS–460]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by September 13, 2016.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov.* Follow the

instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number ________, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of the following:

1. Access CMS' Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995.*
2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*
3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: Reports Clearance Office at (410) 786–1326.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS–339 Provider Cost Report Reimbursement Questionnaire

CMS–460 Medicare Participation Agreement for Physicians and Suppliers

Under the PRA (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Provider Cost Report Reimbursement Questionnaire; *Use:* The information collected in this form (Exhibits 1 and 2) is authorized under Sections 1815(a) and 1833(e) of the Social Security Act, 42 U.S.C. 1395g. Regulations at 42 CFR 413.20 and 413.24 require providers to submit financial and statistical records to verify the cost data disclosed on their annual Medicare cost report. Providers participating in the Medicare program are reimbursed for furnishing covered services to eligible beneficiaries on the basis of an annual cost report (filed with the provider's MAC) in which the proper reimbursement is computed. Consequently, it is necessary to collect this documentation of providers' costs and activities that supports the Medicare cost report data in order to ensure proper Medicare reimbursement to providers. *Form Number:* CMS–339 (OMB control number: 0938–0301); *Frequency:* Yearly; *Affected Public:* Private sector (Business or other For-profits); *Number of Respondents:* 2,273; *Total Annual Responses:* 2,273; *Total Annual Hours:* 15,911. (For policy questions regarding this collection contact Christine Dobrzycki at 410–786–3389.)

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicare Participation Agreement for Physicians and Suppliers; *Use:* Section 1842(h) of the Social Security Act permits physicians and suppliers to voluntarily participate in Medicare Part B by agreeing to take assignment on all claims for services to Medicare beneficiaries. The law also requires that the Secretary provide specific benefits to the physicians, suppliers and other persons who choose to participate. The CMS–460 is the agreement by which the physician or supplier elects to participate in Medicare. *Form Number:* CMS–460 (OMB control number: 0938–0373); *Frequency:* Yearly; *Affected Public:* Private sector (Business or other For-profits); *Number of Respondents:* 120,000; *Total Annual Responses:* 120,000; *Total Annual Hours:* 30,000. (For policy questions regarding this collection contact Mark Baldwin at 410–786–8139.)

Dated: July 12, 2016.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2016–16797 Filed 7–14–16; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3333–N2]

Medicare Program; Announcement of Requirements and Registration for the MIPS Mobile Challenge; Deadline Extension

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice launches a challenge related to the new Merit-based Incentive Payment System (MIPS) program, which will assist the Centers for Medicare & Medicaid Services (CMS) in accelerating the transition from the traditional fee-for-service payment model to a system that rewards health care providers for providing better care, not just more care. This challenge will address one of the most important aspects of our programs, which is educating and providing outreach to the potential hundreds of thousands of MIPS eligible clinicians.

DATES: Important dates concerning the Challenge include the following:

MIPS Mobile Challenge: To be announced on *www.challenge.gov* and opened for submissions in *www.challenge.gov* April 25, 2016.

Deadline for Phase I Submissions: August 15, 2016.

HHS announces top three-five challenge applicants and launches Phase II. Applicants that did not win Phase I will be permitted to compete for Phase II: August 30, 2016.

Deadline for Phase II Submissions: October 31, 2016.

HHS announces grand prize winner: November 15, 2016 (tentative).

FOR FURTHER INFORMATION CONTACT: Stan Ostrow, (410) 786–7207 for inquiry on Information Systems Group.

SUPPLEMENTARY INFORMATION:

I. Background

The Medicare Access and CHIP Reauthorization Act of 2015 (Pub. L. 114–10, enacted April 16, 2015) (MACRA) requires the Secretary to establish a new Merit-based Incentive Payment System (MIPS) program, which will assist the Centers for Medicare & Medicaid Services (CMS) in accelerating the transition from the traditional fee-for-service payment model to a system that rewards health care providers for value rather than volume of services provided. The MIPS program combines parts of the Physician Quality Reporting System, the Value Modifier (VM or Value-based Payment Modifier), and the Medicare Electronic Health Record (EHR) Incentive Program into one single program that assesses the performance of MIPS eligible clinicians based on four performance categories: (1) Quality; (2) Resource use; (3) Clinical practice improvement activities; and (4) Meaningful use of certified EHR technology. This program has the potential of impacting hundreds of thousands of MIPS eligible clinicians.

One of the most important aspects and challenges of our program is educating and providing outreach to the potential hundreds of thousands of MIPS eligible clinicians. Feedback we have received from our customers/end users is that they want more real-time information and access to assistance so they can successfully report to our programs. Therefore, we are launching a MIPS mobile challenge to find innovative ways of improving communication to educate physicians, support staff, health organization leadership, data vendors, and others impacted parties. Due to the multiple user types and facets of the MIPS program we are looking at utilizing a mobile platform, which could be a mobile site or application to determine how to best keep our customers/end users informed and meet their specific needs. We also want to provide the capability to access assistance to help MIPS eligible clinicians learn and get help with specific areas. This challenge has the potential to make a significant impact as not only are there hundreds of thousands of MIPS eligible clinicians but also millions of people who support the success of these MIPS eligible clinicians. Having key information and access to the right support at the right time reduces burden and provides increased satisfaction for the MIPS eligible clinicians and their supporting entities. The challenge will run in the two phases listed below in this section. Phase I participants can move onto Phase II even if their Phase I design was not selected. The focus of the two phases are as follows:

- Phase I: Creation of an initial mobile platform that will feature innovative ways of transmitting educational materials or fostering collaboration among users to provide meaningful education. This will entail creating wireframes, storyboards, mobile screen mock-ups and initial usability testing focused on the design and user experience. In addition, participants will co-design with end users to understand their needs to influence their submission.
- Phase II: Development and functional integration of any features from Phase I, and user experience testing. During this phase, the participants must submit the object and source code, as well as a detailed description showing that the output meets section 508 compliance per the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998 (Pub. L. 105–220, enacted August 7, 1998) (WIA) including at least instructions on how to install and operate, and system requirements for running the mobile platform. Participants may submit, as part of the submission, additional software documentation, if they believe it provides a more complete description of the mobile platforms.

II. Provisions of the Notice

A. Subject of Challenge Competition: MIPS Mobile Challenge

1. Eligibility Rules for Participating in the Competition

To be eligible to win a prize under this challenge, participants (individual or entity) must comply with each and every rule set forth in this section:

1. Shall register to participate in the competition under the rules promulgated below by the Department of Health and Human Services (HHS).
2. In the case of a private entity, shall be incorporated in and maintain a primary place of business in the United States, and in the case of an individual, whether participating individually or in a group, shall be a citizen or permanent resident of the United States.
3. HHS Employees may participate in the MIPS Mobile Challenge, but may not submit in the scope of their employment and may not pursue an application while in the federal workplace or while on duty.
4. Shall not be an employee of the CMS.
5. Federal grantees may not use federal funds to develop the America COMPETES Reauthorization Act of 2010 (Pub. L. 111–358, enacted January 4, 2011) (COMPETES Act) challenge applications unless consistent with the purpose of their grant award.
6. Federal contractors may not use federal funds from a contract to develop COMPETES Act challenge applications or to fund efforts in support of a COMPETES Act challenge submission.
7. Applicants must agree to provide the federal government an irrevocable, royalty-free, non-exclusive worldwide license in the winning work(s) or component parts thereof, in the event that they are prize winner(s). HHS shall be granted the rights to reproduce, distribute copies to the public, publicly display, create derivative works, and publicly post, link to, and share the winning work(s) or parts thereof.

A submission may be disqualified if, in CMS's sole judgment:

- Fails to function as expressed in the detailed description,
- The detailed description is significantly inaccurate or incomplete, or
- Malware or other security threats are present.

Participants agree that we may conduct testing on the submitted code to determine whether malware or other security threats may be present such that they may damage the equipment or operating environments of the Federal Government or those acting on its behalf.

An individual or entity shall not be deemed ineligible because the individual or entity used federal facilities or consulted with federal employees during a competition if the facilities and employees are made available to all individuals and entities participating in the competition on an equitable basis.

Challenge participants will sign a liability release as part of the contest registration process. The liability release will use the following language:

By participating in this competition, I agree to assume any and all risks and waive claims against the federal government and its related entities, except in the case of willing misconduct, for any injury, death, damage, or loss of property, revenue, or profits, whether direct, indirect, or consequential, arising from my participation in this prize contest, whether the injury, death, damage, or loss arises through negligence or otherwise.

B. Selection Process for Participants

1. Amount of the Prize

The top three to five winners for Phase I of the challenge will be provided a monetary cash prize totaling $10,000 per winner. The Phase II final challenge winner will be provided a monetary cash prize totaling $25,000.

2. How Winners Will Be Selected

Challenge submissions will be judged by a panel selected by CMS with relevant expertise in current CMS reporting systems. The expert panel of judges, qualified by training and experience, will evaluate the submissions on the criteria identified below in this section. Judges will be fair and impartial, may not have a personal or financial interest in, or be an employee, officer, director, or agent of, any entity that is a registered participant in the competition, and may not have a personal or financial relationship with an individual who is a registered contestant. The panel will provide expert advice on the merits of each submission to CMS officials responsible for final selections for award. Awardees will be notified on or around the dates listed in the "Date" section. Winners will be selected based on the following criteria:

- Phase 1

++ Ease in which a user can navigate Usability and Design;

++ Evidence of design with User feedback;

++ Innovation in Design; and

++ Look and Feel.

- Phase 2

++ Ease in which a user can navigate Usability and Design;
++ Evidence of design with User feedback;
++ Innovation in Design;
++ Functionality/Accuracy; and
++ Look and Feel.

C. Additional Information

Challenge participants will draw from existing information provided on *www.cms.gov* and collaborate directly with health professionals and/or end users to build their application. The participants will have access to *www.cms.gov* and to end users. Challenge details and registration are located at *www.challenge.gov.*

III. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Dated: June 29, 2016.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2016–16808 Filed 7–14–16; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request; Refugee Microenterprise and Refugee Home-Based Child Care Microenterprise Development

OMB No.: New.

Description: New data collection tool for refugee microenterprise and Refugee Home-Based Child Care Microenterprise Program.

Respondents: Refugee Microenterprise Development Grantees and Refugee Home-Based Child Care Microenterprise Development.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Refugee Microenterprise Development	22	8	4	704
Refugee Home-Based Child Care Microenterprise Development	23	7	4	644
Total Burden				1,348

Estimated Total Annual Burden Hours: (1,340 hours × $30 per hour) $40,440 per year.

Explanation:

The Refugee Microenterprise Development Program

- Currently, there are twenty two grantees (respondents) in the program and the semi-annual progress, which includes the data and information required, is submitted twice per year.
- The request covers one form (Form I. attached) which includes eight data points. Based on experience (the information was provided by technical assistance service provider in the past), it takes about two hours per respondent per six months (*i.e.,* four hours per year per grantee (respondent) or 88 hours per year for all respondents) to complete the form.
- No survey will be undertaken since the collection of this data (information) is part of the implementation process of the project and its collection and reporting does not constitute a separate and additional cost to the grantees (respondents). The cost is covered by the grant the grantee receives. The grantees have Down Home database which captures and stores the data required for reporting. The grantee uploads the semi-annual report in Grant Solution where it is stored. ORR derives the data it requires for reporting and management decision from Grant Solution.

The Refugee Home-Based Child Care Microenterprise Development Group

- Currently, there are twenty three grantees (respondents) in the program and the semi-annual progress.
- The request covers one form (Form II. attached) which includes seven data points. It takes about two hours per respondent per six months (*i.e.,* four hours per year grantee (respondent) or 92 hours per year for all respondents) to complete the form.
- The collection of this data (information) is part of the process and its collection and reporting does not include separate and additional cost to the grantees (respondents). The cost is covered by the grant the grantee receives. The grantees have database which captures and stores the data required for reporting. The grantee uploads the data required in Grant Solution where it is stored. ORR derives the data it requires for reporting and management decision from Grant Solution.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *infocollection@acf.hhs.gov.*

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: *OIRA_SUBMISSION@OMB.EOP.GOV*, Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2016–16700 Filed 7–14–16; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Child Care and Development Fund (CCDF) Tribal Reporting Requirements—ACF–700.

OMB No.: 0970–0430.

Description: The Child Care and Development Fund (CCDF) Tribal Annual Report (ACF–700) requests annual Tribal aggregate information on services provided through the CCDF, which is required by CCDF regulations (45 CFR parts 98 and 99). Tribal Lead Agencies (TLAs) are required to submit annual aggregate data appropriate to Tribal programs on children and families receiving CCDF-funded child care services. The revised ACF–700 report consists of two parts: (1) Administrative Data, and (2) Tribal Narrative. The content and format of the narrative section have been revised to make the form easier to complete with new check box formatting. These revisions will allow the Office of Child Care (OCC) to more easily generate and quantify data in the report. These changes will help us better understand Tribal activities as they relate to compliance, quality of child care, use of funds, and technical assistance needs. Information from the ACF–700 will be included in the Secretary's Report to Congress, as appropriate, and will be shared with all TLAs to inform them of CCDF-funded activities in other Tribal programs. CCDF-funded Tribes that receive their funds under Public Law 102–477 are not required to submit the ACF–700.

Respondents: Tribal Governments.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ACF–700 Report	260	1	38	9,880

Estimated Total Annual Burden Hours: 9,880.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW., Washington, DC 20201. Attention Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *infocollection@acf.hhs.gov.*

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: *OIRA_SUBMISSION@OMB.EOP.GOV*. Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2016–16697 Filed 7–14–16; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–1703]

Principles for Codevelopment of an In Vitro Companion Diagnostic Device With a Therapeutic Product; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Principles for Codevelopment of an In Vitro Companion Diagnostic Device with a Therapeutic Product." This draft guidance is intended to be a practical guide to assist therapeutic product sponsors and in vitro diagnostic device (IVD) sponsors in developing a therapeutic product with an accompanying IVD companion diagnostic, a process referred to as codevelopment. This draft guidance is also intended to assist FDA staff participating in the review of such IVD companion diagnostics or their associated therapeutic products. This draft guidance is not final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment of this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by October 13, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA–2016–D–1703 for "Principles for Codevelopment of an In Vitro Companion Diagnostic Device with a Therapeutic Product; Draft Guidance for Industry and Food and Drug Administration Staff." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- *Confidential Submissions*—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

An electronic copy of the draft guidance s available for download from the Internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance entitled "Principles for Codevelopment of an In Vitro Companion Diagnostic Device with a Therapeutic Product" to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002; or the Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002; or Office of Communications, Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Pamela Bradley, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Silver Spring, MD 20993–0002, 240–731–3734; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240–402–7911; or Christopher Leptak, Center for Drug Evaluation and Research, 10903 New Hampshire Ave., Bldg. 22, Rm. 6462, Silver Spring, MD 20993, 301–796–0017.

SUPPLEMENTARY INFORMATION:

I. Background

This draft guidance is intended to be a practical guide to assist therapeutic product sponsors and IVD sponsors in developing a therapeutic product, with an accompanying IVD companion diagnostic, a process referred to as codevelopment. This draft guidance is also intended to assist FDA staff participating in the review of such IVD companion diagnostics or their associated therapeutic products.

This draft guidance describes general principles to guide codevelopment to support obtaining contemporaneous marketing authorization for a therapeutic product and its corresponding IVD companion diagnostic; certain regulatory requirements that sponsors should be aware of as they develop such products; considerations for planning and executing a therapeutic product clinical trial that also includes the investigation of an IVD companion diagnostic; and administrative issues in the submission process for the therapeutic product and the IVD companion diagnostic.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on "Principles for Codevelopment of an In Vitro Companion Diagnostic Device with a Therapeutic Product." It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* Guidance documents are also available at *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm* or *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.* Persons unable to download an electronic copy of "Principles for Codevelopment of an In Vitro Companion Diagnostic Device with a Therapeutic Product" may send an email request to *CDRH-Guidance@*

fda.hhs.gov to receive an electronic copy of the document. Please use the document number 1400027 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations and guidance documents. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR parts 801 and 809 have been approved under OMB control number 0910–0485; the collections of information in parts 50 and 56 have been approved under OMB control number 0910–0130; the collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078; the collections of information in 21 CFR part 814 subparts B and E have been approved under OMB control number 0910–0231; the collections of information in 21 CFR part 814, subpart H, have been approved under OMB control number 0910–0332; the collections of information in 21 CFR part 807, subpart E, have been approved under OMB control number 0901–0120; the collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073; the collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338; the collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014; the collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001; and the collections of information resulting from special protocol assessments have been approved under OMB control number 0910–0470.

Dated: July 11, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–16735 Filed 7–14–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–1984]

Request for Nominations on the Tobacco Products Scientific Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting that any industry organizations interested in participating in the selection of a nonvoting industry representative of the tobacco manufacturing industry to serve on the Tobacco Products Scientific Advisory Committee for the Center for Tobacco Products (CTP), notify FDA in writing. FDA is also requesting nominations for a nonvoting industry representative of the tobacco manufacturing industry to serve on the Tobacco Products Scientific Advisory Committee, and an alternate to this representative. A nominee may either be self-nominated or nominated by an organization to serve as a nonvoting industry representative. Nominations will be accepted for current vacancies effective with this notice.

DATES: Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests must send a letter stating that interest to the FDA by August 15, 2016 (see sections I and II of this document for further details). Concurrently, nomination materials for prospective candidates should be sent to FDA by August 15, 2016.

ADDRESSES: All statements of interest from industry organizations interested in participating in the selection process should be sent to Caryn Cohen (see **FOR FURTHER INFORMATION CONTACT**). All nominations for nonvoting industry representatives should be submitted electronically by accessing the FDA Advisory Committee Membership Nomination Portal: *https://www.accessdata.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm* or by mail to Advisory Committee Oversight and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5103, Silver Spring, MD 20993–0002. Information about becoming a member of an FDA advisory committee can also be obtained by visiting FDA's Web site *http://www.fda.gov/AdvisoryCommittees/default.htm.*

FOR FURTHER INFORMATION CONTACT: Caryn Cohen, Office of Science, Center for Tobacco Products, Food and Drug Administration, Center for Tobacco Products Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 1–877–287–1373 (choose Option 5), email: *TPSAC@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The Agency intends to add nonvoting industry representatives to the following advisory committee.

I. CTP Advisory Committee, Tobacco Products Scientific Advisory Committee

The Tobacco Products Scientific Advisory Committee (the Committee) advises the Commissioner of Food and Drugs (the Commissioner) or designee in discharging responsibilities related to the regulation of tobacco products. The Committee reviews and evaluates safety, dependence, and health issues relating to tobacco products and provides appropriate advice, information, and recommendations to the Commissioner.

II. Selection Procedure

Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests should send a letter stating that interest to the FDA contact (see **FOR FURTHER INFORMATION CONTACT**) within 30 days of publication of this document (see **DATES**). Within the subsequent 30 days, FDA will send a letter to each organization that has expressed an interest, attaching a complete list of all such organizations and a list of all nominees along with their current resumes. The letter will also state that it is the responsibility of the interested organizations to confer with one another and to select a candidate, within 60 days after the receipt of the FDA letter, to serve as the nonvoting member to represent industry interests for the committee. The interested organizations are not bound by the list of nominees in selecting a candidate. However, if no individual is selected within 60 days, the Commissioner will select the nonvoting member to represent industry interests.

III. Application Procedure

Individuals may self-nominate and/or an organization may nominate one or more individuals to serve as a nonvoting industry representative. Contact information, current curriculum vitae, and the name of the committee of interest should be sent to the FDA Advisory Committee Membership Nomination Portal (see **ADDRESSES**) within 30 days of publication of this document (see **DATES**). FDA will forward all nominations to the organizations expressing interest in participating in the selection process for the committee. (Persons who nominate themselves as nonvoting industry representatives will not participate in the selection process.)

FDA seeks to include the views of women and men, members of all racial and ethnic groups, and individuals with and without disabilities on its advisory committees and, therefore, encourages nominations of appropriately qualified candidates from these groups.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: July 11, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–16739 Filed 7–14–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0508]

Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a revised guidance for industry entitled "Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments." This guidance is intended to assist persons making tobacco product establishment registration and product listing submissions to FDA.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA–2009–D–0508 for "Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of this guidance to the Center for Tobacco Products, Food and Drug Administration, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G335, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the guidance document may be sent. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Katherine Collins, Center for Tobacco Products, Food and Drug Administration, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G335, Silver Spring, MD 20993–0002, email: *CTPRegulations@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a revised guidance for industry entitled, "Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments." This guidance is intended to assist persons making tobacco product establishment registration and product listing submissions to FDA. We are issuing this guidance consistent with our good guidance practices (GGP) regulation (§ 10.115 (21 CFR 10.115)). We are implementing this guidance without prior public comment because we have determined that prior public participation is not feasible or appropriate given the requirement that registration and listing submissions be submitted by December 31, 2016 (§ 10.115(g)(2)). We made this determination because the guidance presents a less burdensome policy consistent with the public health. Although this guidance document is immediately in effect, it remains subject to comment in accordance with FDA''s GGP regulation.

The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111–31) added section 905 to the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 387e), establishing requirements for tobacco product establishment registration and product listing.

FDA revised the registration and listing guidance to include newly deemed tobacco products. Cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco were immediately covered by FDA's tobacco product authorities in chapter IX of the FD&C Act, including section 905, when the Tobacco Control Act went into effect. As for other types of tobacco products, section 901(b) of the FD&C Act (21 U.S.C. 387a) grants FDA authority to deem those products subject to chapter IX of the FD&C Act. Pursuant to that authority, FDA issued a proposed rule seeking to deem all other products that meet the statutory definition of tobacco product, set forth in section 201(rr) of the FD&C Act (21 U.S.C. 321(rr)) (except for accessories of those products) (79 FR 23142). After review and consideration of comments on the proposed rule, FDA published the final rule on May 10, 2016 (81 FR 28974) ("the deeming rule") and it will become effective on August 8, 2016. As a result, owners and operators of domestic establishments engaged in the manufacture, preparation, compounding, or processing of tobacco products subject to the deeming rule are now required to comply with chapter IX of the FD&C Act, including the establishment registration and product listing requirements in section 905.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (§ 10.115). The guidance represents the current thinking of FDA on registration and product listing for owners and operators of domestic tobacco product establishments. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

III. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The time required to complete this information collection is estimated to average 3.75 hours per response, including the time to review instructions, search existing data sources, gather the data needed, and complete and review the information collection. Send comments regarding this burden estimate or suggestions for reducing this burden to: Food and Drug Administration, Center for Tobacco Products, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G335, Silver Spring, MD 20993–0002.

An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this information collection is 0910–0650 (expires June 30, 2019).

IV. Electronic Access

Persons with access to the Internet may obtain an electronic version of the guidance at either *http://www.regulations.gov* or *http://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/default.htm.*

Dated: July 11, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–16734 Filed 7–14–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Council on Graduate Medical Education; Request for Nominations

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Health Resources and Services Administration (HRSA) is requesting nominations to fill vacancies on the Council on Graduate Medical Education (COGME). COGME is authorized by Section 762 of the Public Health Service (PHS) Act (42 U.S.C. 294o), as amended. The Advisory Council is governed by the provisions of the Federal Advisory Act (FACA) (5 U.S.C. Appendix 2), as amended, which sets forth standards for the formation and use of advisory committees, and applies to the extent that the provisions of FACA do not conflict with the requirements of PHS Act Section 762.

DATES: The agency will receive nominations on a continuous basis.

ADDRESSES: All nominations should be submitted to Advisory Council Operations, Bureau of Health Workforce, HRSA, 11W45C, 5600 Fishers Lane, Rockville, Maryland 20857. Mail delivery should be addressed to Advisory Council Operations, Bureau of Health Workforce, HRSA, at the above address, or via email to: *BHWAdvisoryCouncilFRN@hrsa.gov.*

FOR FURTHER INFORMATION CONTACT: Joan Weiss, Ph.D., RN, CRNP, FAAN, Designated Federal Official, COGME at 301–443–0430 or email at *jweiss@hrsa.gov.* A copy of the current committee membership, charter, and reports can be obtained by accessing the Web site *http://www.hrsa.gov/advisorycommittees/bhpradvisory/COGME/index.html.*

SUPPLEMENTARY INFORMATION: COGME provides advice and makes policy recommendations to the Secretary of the U.S. Department of Health and Human Services (Secretary) and ranking members of the Senate Committee on Health, Education, Labor and Pensions, and the U.S. House of Representatives Committee on Energy and Commerce on matters concerning the supply and distribution of physicians in the United States, physician workforce trends, training issues, and financing policies. Meetings are held twice a year.

Specifically, HRSA is requesting nominations for voting members of COGME representing: Practicing primary care physicians, national and specialty physician organizations, foreign medical graduates, medical student and house staff associations, as well as representatives of schools of medicine, schools of osteopathic medicine, public and private teaching hospitals, health insurers, business, and labor. Among these nominations, medical students, residents, and/or fellows from these programs are encouraged to apply.

The Department of Health and Human Services (HHS) will consider nominations of all qualified individuals with the areas of subject matter expertise noted above. Individuals may nominate themselves or other individuals, and professional associations and organizations may nominate one or more qualified persons for membership. Nominations shall state that the nominee is willing to serve as a member of COGME and appears to have no conflict of interest that would preclude COGME membership. Potential candidates will be asked to provide detailed information concerning financial interests, consultancies, research grants, and/or contracts that might be affected by recommendations of COGME to permit evaluation of possible sources of conflicts of interest.

A nomination package should include the following information for each nominee:

(1) A letter of nomination from an employer, a colleague, or a professional organization stating the name, affiliation, and contact information for the nominee, the basis for the nomination (*i.e.,* what specific attributes, perspectives, and/or skills does the individual possess that would benefit the workings of the COGME, and the nominee's field(s) of expertise);

(2) A letter of self-interest stating the reasons the nominee would like to serve on COGME;

(3) A biographical sketch of the nominee and a copy of his/her curriculum vitae; and

(4) The name, address, daytime telephone number, and email address at which the nominator can be contacted. Nominations will be considered as vacancies occur on COGME. Nominations should be updated and resubmitted every 3 years to continue to be considered for committee vacancies. HHS strives to ensure that the membership of HHS federal advisory committees is balanced in terms of points of view represented and the committee's function. The Department encourages nominations of qualified candidates from all groups and locations. Appointment to COGME shall be made without discrimination on the basis of age, race, ethnicity, gender, sexual orientation, disability, and cultural, religious, or socioeconomic status.

Jason E. Bennett,

Director, Division of the Executive Secretariat.

[FR Doc. 2016–16751 Filed 7–14–16; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Availability of the Department of Health and Human Services FY 2015 Service Contract Inventory

AGENCY: Department of Health and Human Services.

ACTION: Notice of public availability of FY 2015 Service Contract Inventories.

SUMMARY: In accordance with Section 743 of Division C of the Consolidated Appropriations Act of 2010 (Pub. L. 111–117), Department of Health and Human Services (HHS) is publishing this notice to advise the public of the availability of its FY 2015 Service Contract Inventory. This inventory provides information on service contract actions over $25,000 that was awarded in FY 2015. The information is organized by function to show how contracted resources are distributed throughout the agency. The inventory has been developed in accordance with guidance issued on November 5, 2010 and December 19, 2011 by the Office of Management and Budget's Office of Federal Procurement Policy (OFPP). OFPP's guidance is available at *http://www.whitehouse.gov/sites/default/files/omb/procurement/memo/service-contract-inventories-guidance-11052010.pdf.* HHS has posted its inventory and a summary of the inventory on the HHS homepage at the following link: *http://www.hhs.gov/grants/contracts/get-ready-to-do-business/service-contract-inventory/index.html.*

FOR FURTHER INFORMATION CONTACT: Questions regarding the service contract inventory should be directed to Dr. Angela Billups, Associate Deputy Assistant Secretary for Acquisition, Senior Procurement Executive HHS/Office of the Secretary, Assistant Secretary for Financial Resources at 202–260–6187 or *Angela.Billups@hhs.gov.*

Angela Billups,

Associate Deputy Assistant Secretary for Acquisition, Senior Procurement Executive, Assistant Secretary for Financial Resources, Office of the Secretary.

[FR Doc. 2016–16802 Filed 7–14–16; 8:45 am]

BILLING CODE 4150–24–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Office of Direct Service and Contracting Tribes; National Indian Health Outreach and Education, Policy/Budget/Diabetes

Announcement Type: Limited New and Competing Continuation.

Funding Announcement Number: HHS–2016–IHS–NIHOE–1–PBD–0001.

Catalog of Federal Domestic Assistance Number: 93.933.

Key Dates

Application Deadline Date: August 15, 2016.

Review Date: August 22, 2016.

Earliest Anticipated Start Date: September 15, 2016.

Proof of Non-Profit Status Due Date: August 15, 2016.

I. Funding Opportunity Description

Statutory Authority

The Indian Health Service (IHS) is accepting competitive cooperative agreement applications for the National Indian Health Outreach and Education, Policy/Budget/Diabetes (NIHOE–I) limited competition cooperative agreement program. This award includes the following four components, as described in this announcement: "Line Item 128 Health Education and Outreach funds," "Health Care Policy Analysis and Review," "Budget Formulation," and "Tribal Leaders Diabetes Committee" (TLDC). This program is authorized under the Snyder Act, codified at 25 U.S.C. 13. The TLDC component is authorized by section 330C of the Public Health Service Act, codified at 42 U.S.C. 254c–3. This program is described in the Catalog of Federal Domestic Assistance under 93.933.

Background

The NIHOE–I program carries out health program objectives in American Indian and Alaska Native (AI/AN) communities in the interest of improving Indian health care for all 567 Federally-recognized Tribes, including Tribal governments operating their own health care delivery systems through self-determination contracts with the IHS and Tribes that continue to receive health care directly from the IHS. This program addresses health policy and health program issues and disseminates educational information to all AI/AN Tribes and villages. This program requires that public forums be held at Tribal educational consumer conferences to disseminate changes and updates in the latest health care information. This program also requires that regional and national meetings be coordinated for information dissemination as well as the inclusion of planning and technical assistance and health care recommendations on behalf of participating Tribes to ultimately inform IHS based on Tribal input through a broad based consumer network.

Purpose

The purpose of this IHS cooperative agreement is to further IHS's mission and goals related to providing quality health care to the AI/AN community through outreach and education efforts with the sole outcome of improving Indian health care. This award includes the following four health services components: Line Item 128 Health Education and Outreach funds, Health Care Policy Analysis and Review, Budget Formulation, and TLDC.

Limited Competition Justification

Competition for the award included in this announcement is limited to national Indian health care organizations with at least ten years of experience providing education and outreach on a national scale. This limitation ensures that the awardee will have: (1) A national information-sharing infrastructure which will facilitate the timely exchange of information between the Department of Health and Human Services (HHS) and Tribes and Tribal organizations on a broad scale; (2) a national perspective on the needs of AI/AN communities that will ensure that the information developed and disseminated through the projects is appropriate, useful and addresses the most pressing needs of AI/AN communities; and (3) established relationships with Tribes and Tribal organizations that will foster open and honest participation by AI/AN communities. Regional or local organizations will not have the mechanisms in place to conduct communication on a national level, nor will they have an accurate picture of the health care needs facing AI/ANs nationwide. Organizations with less experience will lack the established relationships with Tribes and Tribal organizations throughout the country that will facilitate participation and the open and honest exchange of information between Tribes and HHS. With the limited funds available for these projects, HHS must ensure that the education and outreach efforts described in this announcement reach the widest audience possible in a timely fashion, are appropriately tailored to the needs of AI/AN communities throughout the country, and come from a source that AI/ANs recognize and trust. For these reasons, this is a limited competition announcement.

II. Award Information

Type of Award

Cooperative Agreement.

Estimated Funds Available

The total amount of funding identified for the current fiscal period covering (FY) 2016–2018 is approximately $2,475,000 or approximately $825,000 per FY. Three hundred thousand dollars ($300,000) per fiscal year is estimated for outreach, education, and support to Tribes who have elected to leave their Tribal shares with the IHS (this amount could vary based on Tribal shares assumptions; Line Item 128 Health Education and Outreach funding will be awarded in partial increments based on availability and amount of funding); $200,000 per fiscal year for the Health Care Policy Analysis and Review; $75,000 per fiscal year for Budget Formulation; and $250,000 per fiscal year associated with providing legislative education, outreach and communications support to the IHS TLDC and to facilitate Tribal consultation on the Special Diabetes Program for Indians (SDPI). The amount of funding available for both competing and continuation awards issued under this announcement is subject to the availability of appropriations and budgetary priorities of the Agency. The IHS is under no obligation to make awards that are selected for funding under this announcement.

Anticipated Number of Awards

One award will be issued under this program announcement comprised of the following four components: Line Item 128 Health Education and Outreach; Health Care Policy Analysis and Review; Budget Formulation; and TLDC.

Project Period

The project period will run for three years from September 15, 2016 through September 14, 2019.

Cooperative Agreement

Cooperative agreements awarded by HHS are administered under the same policies as a grant. The funding agency (IHS) is required to have substantial programmatic involvement in the project during the entire award segment. Below is a detailed description of the level of involvement required for both IHS and the grantee. IHS will be responsible for activities listed under section A and the grantee will be responsible for activities listed under section B as stated:

Substantial Involvement Description for Cooperative Agreement

A. IHS Programmatic Involvement

1. The IHS assigned program official will work in partnership with the awardee in all decisions involving strategy, hiring of personnel, deployment of resources, release of public information materials, quality assurance, coordination of activities, any training, reports, budget and evaluation. Collaboration includes data analysis, interpretation of findings and reporting.

2. The IHS assigned program official will monitor the overall progress of the awardee's execution of the requirements of the award noted below, as well as their adherence to the terms and conditions of the cooperative agreement. This includes providing guidance for required reports, development of tools and other products, interpreting program findings and assisting with evaluation and overcoming any slippages encountered.

3. The IHS assigned program official will coordinate review and provide final approval of any deliverables, including printed materials, reports, testimony, and PowerPoint slides, prior to their distribution or dissemination to HHS, Tribes, or the public.

4. The IHS assigned program official will also coordinate the following:

- Discussion and release of any and all special grant conditions upon fulfillment.
- Monthly scheduled conference calls.
- Appropriate dissemination of required reports to each participating IHS program.

5. IHS will jointly with the awardee, plan and set an agenda for an annual conference that:

- Shares the outcomes of the outreach and health education training provided.
- Fosters collaboration amongst the participating IHS program offices.
- Increases visibility for the partnership between the awardee and IHS.
- Includes HHS Conference Policy:

6. IHS will provide guidance in preparing articles for publication and/or presentations of program successes, lessons learned and new findings.

7. IHS staff will review articles concerning the HHS for accuracy and may, if requested by the awardee, provide relevant articles.

8. IHS will communicate, via monthly conference calls and meetings, individual or collective (all participating programs) site visits to the awardee.

9. IHS will provide technical assistance to the awardee as requested.

10. IHS staff may, at the request of the entity's board, participate on study groups, attend board meetings, and recommend topics for analysis and discussion.

B. Grantee Cooperative Agreement Award Activities

The awardee must obtain written IHS approval of all deliverables produced with award funds, including printed materials, reports, testimony, and PowerPoint slides, prior to their distribution or dissemination to HHS, Tribes, or the public.

The awardee must comply with relevant Office of Management and Budget (OMB) Circular provisions regarding lobbying, any applicable lobbying restrictions provided under other law and any applicable restriction on the use of appropriated funds for lobbying activities.

Pre-Conference Grants

1. Pre-Conference Grant Requirements. The awardee is required to comply with the "HHS Policy on Promoting Efficient Spending: Use of Appropriated Funds for Conferences and Meeting Space, Food, Promotional Items, and Printing and Publications," dated December 16, 2013 ("Policy"), as applicable to conferences funded by grants and cooperative agreements. The Policy is available at *http://www.hhs.gov/asfr/ogapa/acquisition/policies/promoting-efficient-conference-spending-policy-12-16-2013.html.*

The awardee is required to:

Provide a separate detailed budget justification and narrative for each conference anticipated. The cost categories to be addressed are as follows: (1) Contract/Planner, (2) Meeting Space/Venue, (3) Registration Web site, (4) Audio Visual, (5) Speakers Fees, (6) Non-Federal Attendee Travel, (7) Registration Fees, (8) Other (explain in detail and cost breakdown). For additional questions please contact Ms. Michelle EagleHawk on (301) 443–1104 or email her at *Michelle.EagleHawk@ihs.gov.*

2. Line Item 128 Health Education and Outreach funding is utilized for outreach, health education, and support to Tribes—approximately $300,000 per fiscal year funding is available totaling $900,000.

The awardee is expected to fulfill the following:

Meeting Responsibilities ANNUAL (Required)

Estimated Costs: The estimated costs for this activity shall not exceed $100,000 per fiscal year. The awardee shall work with IHS/Office of Direct Service and Contracting Tribes (ODSCT) closely on this item. As the sponsoring agency, IHS meeting attendees will not incur registration fees.

a. Host an annual conference to disseminate changes and updates on health care information relative to AI/AN.

Meeting Responsibilities MID-YEAR (Required)

Estimated Costs: The estimated costs for this activity shall not exceed $100,000 per fiscal year. The awardee shall work with IHS/ODSCT closely on this item. As the sponsoring agency, IHS meeting attendees will not incur registration fees.

a. Host a mid-year consumer conference(s) as appropriate to disseminate changes and updates on health care information relative to AI/AN.

Coordination, Dissemination, and Technical Assistance Responsibilities (Required)

Estimated Costs: The estimated costs for this activity shall not exceed $100,000 per fiscal year. The awardee shall work with IHS/ODSCT closely on this item.

a. Conduct regional and national meeting coordination as appropriate.

b. Conduct health care information dissemination as appropriate.

c. Coordinate planning and technical assistance needs on behalf of Tribes/Tribal organizations (T/TO) with IHS.

d. Convey health care recommendations on behalf of T/TO to IHS.

3. Health Care Policy Analysis and Review.

This funding component requires the awardee to provide IHS with research and analysis of the impact of Centers for Medicare and Medicaid Services (CMS) programs on AI/AN beneficiaries and the health care delivery system that serves these beneficiaries. $200,000 funding is available per fiscal year totaling $600,000 for analysis of CMS programs that affect AI/AN beneficiaries.

The awardee will produce measurable outcomes to include:

a. Analytical reports, policy review and recommendation documents—The products will be in the form of written (hard copy and/or electronic files) documents that contain analysis of relevant health care issues to be reported on a monthly or quarterly basis and face-to-face meetings with hard copies submitted to the Director, IHS/Office of Resource, Access and Partnerships (ORAP).

b. Qualitative and quantitative analysis of the overall impact of the Affordable Care Act (ACA) implementation, including the regulations and policies, on the Indian health care system, in terms of whether or not it is working as intended. That is, whether Tribes and AI/AN consumers are receiving the benefits of the special provisions for Indians, and whether all of the necessary stakeholders including Indian Health Service/Tribes/Urbans (I/T/Us), qualified health plans, providers, and consumers have the information and capacity to ensure successful outcomes and are working cooperatively and effectively to that end.

c. Policy recommendations, based on the analysis, that include in particular, direct service Tribes' perspectives incorporating real-time information on how the structure of the Federal system should support the I/T/U healthcare delivery system. If deficiencies are found, provide recommendations on improvement and solutions. Issues of analysis may include improving access to care, obtaining affordable coverage, network contracting and enforcement of Section 206 of the Indian Health Care Improvement Act (IHCIA).

d. Educational and informational materials to be disseminated by the awardee and communicated to IHS and Tribal health program staff during monthly and quarterly conferences, the annual consumer conference, meetings and training sessions. This can be in the form of PowerPoint presentations, informational brochures, and/or handout materials.

The IHS will provide guidance and assistance as needed. Copies of all deliverables shall be submitted to the IHS/ODSCT and IHS/ORAP.

4. Tribal Budget Consultation—Budget Formulation.

The awardee will provide assistance and technical support to IHS, Tribes, and the Budget Formulation Workgroup with the National Budget Formulation work session, the HHS Tribal Consultation meeting, and the Budget Formulation Evaluation and Planning meeting. The awardee will develop the National Tribal Budget Recommendation document, briefing documents, and Tribal Leaders presentation and talking points, by performing the activities described below in coordination with and support of the IHS Tribal Budget Consultation process. $75,000 is available per fiscal year for Budget Formulation. Budget consultation is required by the Indian Self-Determination and Education Assistance Act, 25 U.S.C. 450j–1(i).

NATIONAL BUDGET FORMULATION WORK SESSION—January 2017–2019 Meeting Responsibilities (Required)

Estimated Costs: The estimated costs for this activity shall not exceed $10,000 per fiscal year. The awardee shall work with IHS/Office of Finance and Accounting (OFA)/Division of Budget Formulation (DBF) closely on this item.

a. Registration of National Budget Formulation Work Session attendees. The Awardee shall assist with the registration of all attendees as they enter the Budget Formulation Work Session.

b. The awardee shall distribute prepared budget formulation packages to all attendees.

Recordation of Meeting—The awardee shall take minutes during the work session.

a. Minutes should be recorded in a clear and concise manner and identify all speakers including presenters and any individuals contributing comments or motions.

b. Minutes will be recorded in an objective manner.

c. Minutes shall include a record of any comments, votes, or recommendations made, as well as notation of any handouts and other materials referenced by speakers, documented by the speaker's name and affiliation.

d. Minutes shall document any written materials that were distributed at the meeting. These materials will be included with the submission of the transcription and the summary page outlining all key topics.

e. Minutes will include information regarding the next meeting, including the date, time and location and a list of topics to be addressed.

f. The minutes must be submitted to IHS/OFA in final draft within five working days after the conclusion of the work session.

Further Instructions

The awardee shall:

a. Package and distribute results of the work session to IHS/OFA within five working days, which includes minutes and the final set of agreed upon national budget priorities; and

b. Provide final documents needed for the IHS budget formulation Web site.

HHS Tribal Consultation—March 2017–2019

Preparation and Meeting Responsibilities

Estimated Costs: The estimated costs for this activity shall not exceed $55,000 per fiscal year. The awardee shall work with IHS/OFA/DBF closely on this item.

The Tribal testimony is a combined effort that is written and presented by the National Tribal Budget Formulation Workgroup. The testimony is presented to the Secretary of HHS and related staff as part of the Annual National U.S. Department of Health and Human Services Tribal Budget and Policy Consultation.

The awardee will assist the National Tribal Budget Formulation Workgroup to prepare for the HHS Consultation meeting by:

a. Arranging a workgroup meeting;

b. Preparing testimony and a PowerPoint presentation with talking points, with the content of both based on input from the workgroup and technical team and with the awardee responsible for formatting and design of the products;

c. Submitting testimony and the draft PowerPoint presentation to IHS for review and clearance ten working days prior to the presentation to HHS;

d. Packaging and distributing final materials, once clearance from IHS is obtained; and

e. Delivering the final testimony to the IHS/OFA/DBF five working days prior to the presentation.

The awardee will arrange working space for the workgroup to provide final input to the presentation and finalize the presentation, if needed—not to exceed two days. In addition, the awardee will assist presenters, as needed, with rehearsal of the final presentation.

Budget Formulation Evaluation and Planning Meeting—May 2017–2019

Meeting Responsibilities (Required)

Estimated Costs: The estimated costs for this activity shall not exceed $10,000 per fiscal year. The awardee shall work with IHS/OFA/DBF closely on this item.

Recordation of Meeting—The awardee shall take minutes during the work session.

a. Minutes should be recorded in a clear and concise manner and identify all speakers including presenters and any individuals contributing comments or motions.

b. Minutes will be recorded in an objective manner.

c. Minutes shall include a record of any comments, votes, or recommendations made, as well as notation of any handouts and other materials referenced by speakers, documented by the speaker's name and affiliation.

d. Minutes shall document any written materials that were distributed at the meeting. These materials will be included with the submission of the transcription and the summary page outlining all key topics.

e. Minutes will include information regarding the next meeting, including the date, time and location and a list of topics to be addressed.

f. The minutes must be submitted to IHS/OFA in final draft within five working days after the conclusion of the meeting.

Further Instructions

The awardee shall package and distribute results of the meeting in final:

a. To OFA within five working days; and

b. The documents needed for IHS budget formulation Web site.

Additionally, for all specified meeting and activities:

- All expenses will be itemized.
- If costs are projected to exceed the estimated cost for any part of this Scope of Work, approval from IHS/OFA must be granted before any release of funds.
- Preapproval from IHS is required before any subcontract may be awarded at a price above the estimated cost.

5. Provide Support for TLDC Meetings and Provide Education, Outreach and Communications Support.

A total of $250,000 per fiscal year totaling $750,000 is available for tasks associated with providing meeting support for the TLDC and providing education, outreach and communications support on the activities of the TLDC, the SDPI grant program and related diabetes/chronic disease issues.

TLDC Meetings

Meeting Responsibilities (Required)

Estimated Costs: The estimated costs for this activity shall not exceed $184,000 per year or $46,000 per face-to-face meeting. The awardee shall work with the Division of Diabetes Treatment and Prevention (DDTP) closely on this item.

a. Provide logistical support for TLDC meetings and workgroup sessions.

i. Face-to-Face TLDC meetings (up to quarterly).

1. Location to be determined by TLDC members and the IHS Principal Deputy Director or designee. Every effort will be made to utilize Federal meeting space for TLDC meetings where appropriate.

2. In consultation with DDTP, provide timely pre-meeting logistical support for TLDC meetings, including reserving TLDC meeting space, establishing hotel sleeping room block(s) at government per diem rate for all meeting attendees, setting up transportation for attendees if sleeping rooms are at a location separate from the meeting site, and other support services as needed to ensure the smooth and timely organization of TLDC meetings.

(a) Note that, for the purpose of this cooperative agreement, TLDC meeting attendees include TLDC members/alternates, TLDC advisors, federal participants (*e.g.,* IHS leadership, DDTP staff, Area Diabetes Consultants, non-IHS federal professionals), invited meeting speakers, and others who might reasonably be expected to participate in a TLDC meeting or who are otherwise invited to attend.

3. Provide on-site logistical support for TLDC meetings, including coordination of meeting activities; provision of appropriate audiovisual equipment, including sufficient number and type of microphones (*i.e.* podium, tabletop, lavalier), laptop computer with internet connection, projector/screen; room set-up; registration services; and materials (*e.g.,* badges, name tents, paper flip charts, and agendas and other meeting documents).

ii. TLDC Workgroups

1. When requested by DDTP, schedule conference calls and/or webinars for four TLDC workgroups.

2. Record and provide minutes of TLDC workgroup sessions.

Minutes will be completed as follows:

(a) Minutes will be recorded in a clear and concise manner and identify all speakers including presenters and any individuals contributing comments or motions.

(b) Minutes will be recorded in an objective manner.

(c) Minutes shall include a record of any comments or recommendations made, as well as notation of any handouts and other materials referenced by speakers, documented by the speaker's name and affiliation.

(d) Minutes shall document any written materials that were distributed at the meeting.

(e) Minutes will include information regarding the next meeting, including the date, time and location, and a list of topics to be addressed.

(f) The minutes must be submitted to DDTP for review and approval within five working days after each TLDC workgroup meeting.

(g) Provide final minutes and pertinent documents to DDTP within five working days of receiving DDTP's edits on the draft versions.

b. Coordinate travel planning and travel/per diem reimbursement in accordance with the approved TLDC charter for 12 TLDC members (or their assigned alternate) and five technical advisors to attend up to four quarterly TLDC meetings per year. Additionally, coordinate travel planning and travel/per diem reimbursement for up to two IHS-approved non-Federal speakers per TLDC in-person meeting.

i. Travel planning and reimbursement process will include:

1. Direct communication with TLDC members (and alternates, as necessary), technical advisors, and speakers to assist in travel arrangements.

2. Provide logistical information to TLDC members, advisors, and speakers for meeting location and lodging.

3. Prepare and distribute reimbursement forms with clear instructions in advance of the meeting and serve as the point of contact for communicating any additional travel information that is required.

4. Collect reimbursement forms and provide timely reimbursement of approved participants' expenses within 30 days of the receipt of the claim forms.

5. Provide a detailed travel reimbursement report to DDTP within 60 days of the TLDC meeting.

6. Maintain an active TLDC email directory in order to assist DDTP and TLDC with disseminating related meeting, travel and reimbursement information and soliciting related feedback.

7. Include identified DDTP staff on all email correspondence to TLDC members and technical advisors.

Provide Education, Outreach, and Communications Support Responsibilities (Required)

Estimated Costs: The estimated cost for these activities is $66,000 per fiscal year. The awardee shall work with DDTP closely on this item.

a. Communicate with Tribal leaders and Indian organizations about the activities of the TLDC, the SDPI grant program, and related diabetes/chronic disease issues.

i. Provide factual information, review and analysis of legislative and policy issues that are relevant to diabetes and related chronic conditions in AI/ANs and on related health care disparities in written and email format for the purpose of keeping TLDC membership up-to-date on such information and for sharing with other Tribal leadership, Indian organizations, and others.

ii. Coordinate sharing DDTP-approved information with national non-profit organizations, such as the Juvenile Diabetes Research Foundation and the American Diabetes Association, for the purpose of strengthening outreach to Tribes and Tribal communities as well as education and outreach to non-Indian communities in the United States about AI/ANs living with diabetes and other chronic diseases.

iii. Support registration, presentation, and exhibit costs for up to five DDTP staff and assignees to potentially include a plenary and up to four workshop presentations on diabetes, SDPI, and related chronic disease at meetings such as:

1. National Indian Health Board (NIHB) Public Health Summit and the NIHB Annual Consumer Conference; and

2. Other national Tribal health care conferences/meetings such as the National Congress of American Indians Annual Convention.

iv. Support exhibit opportunity for SDPI grant programs to display programmatic information at the 2017–2020 NIHB Public Health Summits.

III. Eligibility Information

I.

1. Eligibility

To be eligible for this "New/Competing Continuation Announcement," an eligible applicant must be a 501(c)(3) national Indian organization that has demonstrated expertise as follows:

- Representing all Tribal governments and providing a variety of services to Tribes, area health boards, Tribal organizations, and Federal agencies, and playing a major role in focusing attention on Indian health care needs, resulting in improved health outcomes for Tribes.
- Promoting and supporting Indian education and coordinating efforts to inform AI/AN of Federal decisions that affect Tribal government interests including the improvement of Indian health care.
- Administering national health policy and health programs.
- Maintaining a national AI/AN constituency and clearly supporting critical services and activities within the IHS mission of improving the quality of health care for AI/AN people.
- Supporting improved healthcare in Indian Country.

Applicants must provide proof of non-profit status with the application. The national Indian organization must have the infrastructure in place to accomplish the work under the proposed program.

Note: Please refer to Section IV.2 (Application and Submission Information/Subsection 2, Content and Form of Application Submission) for additional proof of applicant status documents required such as Tribal resolutions, proof of non-profit status, etc.

2. Cost Sharing or Matching

The IHS does not require matching funds or cost sharing for grants or cooperative agreements.

3. Other Requirements

If application budgets exceed the highest dollar amount outlined under the "Estimated Funds Available" section within this funding announcement, the application will be considered ineligible and will not be reviewed for further consideration. If deemed ineligible, IHS will not return the application. The applicant will be notified by email by the Division of Grants Management (DGM) of this decision.

The following documentation is required:

Proof of Non-Profit Status

Organizations claiming non-profit status must submit proof. A copy of the 501(c)(3) Certificate must be received with the application submission by the Application Deadline Date listed under the Key Dates section on page one of this announcement.

An applicant submitting any of the above additional documentation after the initial application submission due date is required to ensure the information was received by the IHS by obtaining documentation confirming delivery (*i.e.,* FedEx tracking, postal return receipt, etc.).

IV. Application and Submission Information

1. Obtaining Application Materials

The application package and detailed instructions for this announcement can be found at *http://www.Grants.gov* or *http://www.ihs.gov/dgm/funding/.*

Questions regarding the electronic application process may be directed to Mr. Paul Gettys at (301) 443–2114 or (301) 443–5204.

2. Content and Form Application Submission

The applicant must include the project narrative as an attachment to the application package. Mandatory documents for all applicants include:

- Table of contents.
- Abstract (one page) summarizing the project.
- Application forms:
  - ○ SF–424, Application for Federal Assistance.
  - ○ SF–424A, Budget Information—Non-Construction Programs.
  - ○ SF–424B, Assurances—Non-Construction Programs.
- Budget Justification and Narrative (must be single spaced and not exceed five pages).
- Project Narrative (must be single spaced and not exceed ten pages for each of the four components listed).
  - ○ Background information on the organization.
  - ○ Proposed scope of work, objectives, and activities that provide a description of what will be accomplished, including a one-page Timeframe Chart.
- Letter of support from organization's Board of Directors.
- 501(c)(3) Certificate (if applicable).
- Position descriptions for key personnel.
- Resumes of key personnel.
- Contractor/Consultant resumes or qualifications and scope of work.
- Disclosure of Lobbying Activities (SF–LLL).
- Certification Regarding Lobbying (GG-Lobbying Form).
- Copy of current Negotiated Indirect Cost rate (IDC) agreement (required) in order to receive IDC.
- Organizational chart (optional).
- Documentation of current OMB A–133 or other required Financial Audit (if applicable).

Acceptable forms of documentation include:

- ○ Email confirmation from Federal Audit Clearinghouse (FAC) that audits were submitted; or
- ○ Face sheets from audit reports. These can be found on the FAC Web site: *http://harvester.census.gov/sac/dissem/accessoptions.html?submit=Go+To+Database.*

Public Policy Requirements

All Federal-wide public policies apply to IHS grants and cooperative agreements with exception of the discrimination policy.

Requirements for Project and Budget Narratives

A. Project Narrative: This narrative should be a separate Word document that is no longer than ten pages per each component and must: Be single-spaced, be type written, have consecutively numbered pages, use black type not smaller than 12 characters per one inch, and be printed on one side only of standard size 8–1/2'' × 11'' paper.

Be sure to succinctly address and answer all questions listed under each part of the narrative and place all responses and required information in the correct section (noted below), or they shall not be considered or scored. These narratives will assist the Objective Review Committee (ORC) in becoming familiar with the applicant's activities and accomplishments prior to this grant award. If the narrative exceeds the page limit, only the first ten pages of each of the four components will be reviewed. The ten pages per component page limit for the narrative does not include the work plan, standard forms, table of contents, budget, budget narrative justifications, and/or other appendix items.

There are three parts to the narrative: Part A—Program Information; Part B—Program Planning and Evaluation; and Part C—Program Report. See below for additional details about what must be included in the narrative.

Part A: Program Information (2 page limitation)

Section 1: Needs

Describe how the national Indian organization has the expertise to provide outreach and education efforts on a continuing basis regarding the pertinent changes and updates in health care for each of the four components listed herein.

Part B: Program Planning and Evaluation (6 page limitation)

Section 1: Program Plans

Describe fully and clearly how the national Indian organization plans to address the NIHOE1 requirements, including how the national Indian organization plans to demonstrate improved health education and outreach services to all 567 Federally-recognized Tribes for each of the four components described herein. Include proposed timelines as appropriate and applicable.

Section 2: Program Evaluation

Describe fully and clearly how the outreach and education efforts will impact changes in knowledge and awareness in Tribal communities. Identify anticipated or expected benefits for the Tribal constituency.

Part C: Program Report (2 page limitation)

Section 1: Describe major accomplishments over the last 24 months. Please identify and describe significant program achievements associated with the delivery of quality health outreach and education services for each of the four components. Provide a comparison of the actual accomplishments to the goals established for the project period, or if applicable, provide justification for the lack of progress.

Section 2: Describe major activities over the last 24 months. Please identify and summarize recent major health related project activities of the work done regarding each of the four components during the project period.

B. Budget Narrative: This narrative must include a line item budget with a narrative justification for all expenditures identifying reasonable and allowable costs necessary to accomplish the goals and objectives as outlined in the project narrative. The budget narrative should match the scope of work described in the project narrative. The budget narrative should not exceed five pages.

3. Submission Dates and Times

Applications must be submitted electronically through *Grants.gov* by 11:59 p.m., Eastern Daylight Time (EDT) on the Application Deadline Date listed in the Key Dates section on page one of this announcement. Any application received after the application deadline will not be accepted for processing, nor will it be given further consideration for funding. *Grants.gov* will notify the applicant via email if the application is rejected.

If technical challenges arise and assistance is required with the electronic application process, contact *Grants.gov* Customer Support via email to *support@grants.gov* or at (800) 518–4726. Customer support is available to address questions 24 hours a day, 7 days a week (except on Federal holidays). If problems persist, contact Mr. Paul Gettys (*Paul.Gettys@ihs.gov*), DGM Grant Systems Coordinator, by telephone at (301) 443–2114 or (301) 443–5204. Please be sure to contact Mr. Gettys at least ten days prior to the application deadline. Please do not contact the DGM until you have received a *Grants.gov* tracking number. In the event you are not able to obtain a tracking number, call the DGM as soon as possible.

If the applicant needs to submit a paper application instead of submitting electronically through *Grants.gov*, a waiver must be requested. Prior approval must be requested and obtained from Mr. Robert Tarwater, Director, DGM, (see Section IV.6 below for additional information). The waiver must: (1) Be documented in writing (emails are acceptable), *before* submitting a paper application, and (2) include clear justification for the need to deviate from the required electronic grants submission process. A written waiver request must be sent to *GrantsPolicy@ihs.gov* with a copy to *Robert.Tarwater@ihs.gov*. Once the waiver request has been approved, the applicant will receive a confirmation of approval email containing submission instructions and the mailing address to submit the application. A copy of the written approval *must* be submitted along with the hardcopy of the application that is mailed to DGM. Paper applications that are submitted without a copy of the signed waiver from the Senior Policy Analyst of the DGM will not be reviewed or considered for funding. The applicant will be notified via email of this decision by the Grants Management Officer of the DGM. Paper applications must be received by the DGM no later than 5:00 p.m., EDT, on the Application Deadline Date listed in the Key Dates section on page one of this announcement. Late applications will not be accepted for processing or considered for funding.

4. Intergovernmental Review

Executive Order 12372 requiring intergovernmental review is not applicable to this program.

5. Funding Restrictions

- Pre-award costs are not allowable.
- The available funds are inclusive of direct and appropriate indirect costs.
- Only one grant/cooperative agreement will be awarded per applicant.
- IHS will not acknowledge receipt of applications.

6. Electronic Submission Requirements

All applications must be submitted electronically. Please use the *http://www.Grants.gov* Web site to submit an application electronically and select the "Find Grant Opportunities" link on the homepage. Download a copy of the application package, complete it offline, and then upload and submit the completed application via the *http://www.Grants.gov* Web site. Electronic copies of the application may not be submitted as attachments to email messages addressed to IHS employees or offices.

If the applicant receives a waiver to submit paper application documents, the applicant must follow the rules and timelines that are noted below. The applicant must seek assistance at least ten days prior to the Application Deadline Date listed in the Key Dates section on page one of this announcement.

Applicants that do not adhere to the timelines for System for Award Management (SAM) and/or *http://www.Grants.gov* registration or that fail to request timely assistance with technical issues will not be considered for a waiver to submit a paper application.

Please be aware of the following:

- Please search for the application package in *http://www.Grants.gov* by entering the CFDA number or the Funding Opportunity Number. Both numbers are located in the header of this announcement.
- If you experience technical challenges while submitting your application electronically, please contact *Grants.gov* Support directly at: *support@grants.gov* or (800) 518–4726. Customer support is available to address questions 24 hours a day, 7 days a week (except on Federal holidays).
- Upon contacting *Grants.gov*, obtain a tracking number as proof of contact. The tracking number is helpful if there are technical issues that cannot be resolved and a waiver from the agency must be obtained.
- If it is determined that a waiver is needed, the applicant must submit a request in writing (emails are acceptable) to *GrantsPolicy@ihs.gov* with a copy to *Robert.Tarwater@ihs.gov*. Please include a clear justification for the need to deviate from the standard electronic submission process.
- If the waiver is approved, the application should be sent directly to the DGM by the Application Deadline Date listed in the Key Dates section on page one of this announcement.
- Applicants are strongly encouraged not to wait until the deadline date to begin the application process through *Grants.gov* as the registration process for SAM and *Grants.gov* could take up to fifteen working days.
- Please use the optional attachment feature in *Grants.gov* to attach additional documentation that may be requested by the DGM.
- All applicants must comply with any page limitation requirements described in this funding announcement.
- After electronically submitting the application, the applicant will receive an automatic acknowledgment from *Grants.gov* that contains a *Grants.gov* tracking number. The DGM will download the application from *Grants.gov* and provide necessary copies to the appropriate agency officials. Neither the DGM nor the ODSCT will notify the applicant that the application has been received.
- Email applications will not be accepted under this announcement.

Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS)

All IHS applicants and grantee organizations are required to obtain a DUNS number and maintain an active registration in the SAM database. The DUNS number is a unique 9-digit identification number provided by D&B which uniquely identifies each entity. The DUNS number is site specific; therefore, each distinct performance site may be assigned a DUNS number. Obtaining a DUNS number is easy, and there is no charge. To obtain a DUNS number, please access it through *http://fedgov.dnb.com/webform*, or to expedite the process, call (866) 705–5711.

All HHS recipients are required by the Federal Funding Accountability and Transparency Act of 2006, as amended ("Transparency Act"), to report information on sub-awards. Accordingly, all IHS grantees must notify potential first-tier sub-recipients that no entity may receive a first-tier sub-award unless the entity has provided its DUNS number to the prime grantee organization. This requirement ensures the use of a universal identifier to enhance the quality of information available to the public pursuant to the Transparency Act.

System for Award Management (SAM)

Organizations that were not registered with Central Contractor Registration and have not registered with SAM will need to obtain a DUNS number first and then access the SAM online registration through the SAM home page at *https://www.sam.gov* (U.S. organizations will also need to provide an Employer Identification Number from the Internal Revenue Service that may take an additional 2–5 weeks to become active). Completing and submitting the registration takes approximately one hour to complete and SAM registration will take 3–5 business days to process. Registration with the SAM is free of charge. Applicants may register online at *https://www.sam.gov.*

Additional information on implementing the Transparency Act, including the specific requirements for DUNS and SAM, can be found on the IHS Grants Management, Grants Policy Web site: *http://www.ihs.gov/dgm/policytopics/.*

V. Application Review Information

The instructions for preparing the application narrative also constitute the evaluation criteria for reviewing and scoring the application. Weights assigned to each section are noted in parentheses. The ten page narrative allowed per each of the four components page narrative should include only the first year of activities; information for multi-year projects should be included as an appendix. See "Multi-year Project Requirements" at the end of this section for more information. The narrative section should be written in a manner that is clear to outside reviewers unfamiliar with prior related activities of the applicant. It should be well organized, succinct, and contain all information necessary for reviewers to understand the project fully. Points will be assigned to each evaluation criteria adding up to a total of 100 points. A minimum score of 60 points is required for funding. Points are assigned as follows:

1. Criteria

A. Introduction and Need for Assistance (15 points)

(1) Describe the organization's current health, education and technical assistance operations as related to the broad spectrum of health needs of the AI/AN community. Include what programs and services are currently provided (*i.e.,* Federally-funded, State-funded, etc.), any memorandums of agreement with other national, area or local Indian health board organizations. This could also include HHS agencies that rely on the applicant as the primary gateway organization to AI/AN communities that are capable of providing the dissemination of health information. Include information regarding technologies currently used (*i.e.,* hardware, software, services, Web sites, etc.), and identify the source(s) of technical support for those technologies (*i.e.,* in-house staff, contractors, vendors, etc.). Include information regarding how long the applicant has been operating and its length of association/partnerships with area health boards, etc. [historical collaboration].

(2) Describe the organization's current technical assistance ability. Include what programs and services are currently provided, programs and services projected to be provided, memorandums of agreement with other national Indian organizations that deem the applicant as the primary source of health policy information for AI/AN, memorandums of agreement with other area Indian health boards, etc.

(3) Describe the population to be served by the proposed projects.

(4) Identify all previous IHS cooperative agreement awards received, dates of funding and summaries of the projects' accomplishments. State how previous cooperative agreement funds facilitated education, training and technical assistance nationwide for AI/ANs and relate the progression of health care information delivery and development relative to the current proposed projects. (Copies of reports will not be accepted.)

(5) Describe collaborative and supportive efforts with national, area and local Indian health boards.

(6) Explain the need/reason for your proposed projects by identifying specific gaps or weaknesses in services or infrastructure that will be addressed by the proposed projects. Explain how these gaps/weaknesses have been assessed.

(7) If the proposed projects include information technology (*i.e.,* hardware, software, etc.), provide further information regarding measures taken or to be taken that ensure the proposed projects will not create other gaps in services or infrastructure (*i.e.,* negatively or adversely affect IHS interface capability, Government Performance Results Act reporting requirements, contract reporting requirements, information technology compatibility, etc.), if applicable.

(8) Describe the effect of the proposed projects on current programs (*i.e.,* Federally-funded, State-funded, etc.) and, if applicable, on current equipment (*i.e.,* hardware, software, services, etc.). Include the effect of the proposed projects on planned/anticipated programs and/or equipment.

(9) Describe how the projects relate to the purpose of the cooperative agreement by addressing the following: Identify how the proposed projects will address outreach and education regarding each of the four components: Line Item 128 Health Education and Outreach funds, Health Care Policy Analysis and Review, Budget Formulation, and TLDC.

B. Project Objective(s), Work Plan and Approach (40 points)

(1) Identify the proposed objective(s) for each of the four projects, as applicable. Objectives should be:

- Measurable and (if applicable) quantifiable.
- Results oriented.
- Time-limited.

Example: Issue four quarterly newsletters, provide alerts and quantify number of contacts with Tribes.

Goals must be clear and concise. Objectives must be measurable, feasible and attainable for each of the selected projects.

(2) Address how the proposed projects will result in change or improvement in program operations or processes for each proposed project objective for all of the projects. Also address what tangible products, if any, are expected from the projects, (*i.e.,* policy analysis, annual conference, mid-year conferences, summits, etc.).

(3) Address the extent to which the proposed projects will provide, improve, or expand services that address the need(s) of the target population. Include a current strategic plan and business plan that includes the expanded services. Include the plan(s) with the application submission.

(4) Submit a work plan in the appendix which includes the following information:

- Provide the action steps on a timeline for accomplishing each of the projects' proposed objective(s).
- Identify who will perform the action steps.
- Identify who will supervise the action steps.
- Identify what tangible products will be produced during and at the end of the proposed projects' objective(s).
- Identify who will accept and/or approve work products during the duration of the proposed projects and at the end of the proposed projects.
- Include any training that will take place during the proposed projects and who will be attending the training.
- Include evaluation activities planned in the work plans.

(5) If consultants or contractors will be used during the proposed project, please include the following information in their scope of work (or note if consultants/contractors will not be used):

- Educational requirements.
- Desired qualifications and work experience.
- Expected work products to be delivered on a timeline.

If a potential consultant/contractor has already been identified, please include a resume in the Appendix.

(6) Describe what updates will be required for the continued success of the proposed projects. Include when these updates are anticipated and where funds will come from to conduct the update and/or maintenance.

C. Program Evaluation (20 points)

Each proposed objective requires an evaluation component to assess its progression and ensure its completion. Also, include the evaluation activities in the work plan.

Describe the proposed plan to evaluate both outcomes and process. Outcome evaluation relates to the results identified in the objectives, and process evaluation relates to the work plan and activities of the project.

(1) For outcome evaluation, describe:

- What will the criteria be for determining success of each objective?
- What data will be collected to determine whether the objective was met?
- At what intervals will data be collected?
- Who will collect the data and their qualifications?
- How will the data be analyzed?
- How will the results be used?

(2) For process evaluation, describe:

- How will each project be monitored and assessed for potential problems and needed quality improvements?
- Who will be responsible for monitoring and managing each project's improvements based on results of ongoing process improvements and their qualifications?
- How will ongoing monitoring be used to improve the projects?
- Describe any products, such as manuals or policies, that might be developed and how they might lend themselves to replication by others.
- How will the organization document what is learned throughout each of the projects' periods?

(3) Describe any evaluation efforts planned after the grant period has ended.

(4) Describe the ultimate benefit to the AI/AN population that the applicant organization serves that will be derived from these projects.

D. Organizational Capabilities, Key Personnel and Qualifications (15 points)

This section outlines the broader capacity of the organization to complete the project outlined in the work plan. It includes the identification of personnel responsible for completing tasks and the chain of responsibility for successful completion of the projects outlined in the work plan.

(1) Describe the organizational structure of the organization beyond health care activities, if applicable.

(2) Describe the ability of the organization to manage the proposed projects. Include information regarding similarly sized projects in scope and financial assistance, as well as other cooperative agreements/grants and projects successfully completed.

(3) Describe what equipment (*i.e.,* fax machine, phone, computer, etc.) and facility space (*i.e.,* office space) will be available for use during the proposed projects. Include information about any equipment not currently available that will be purchased through the cooperative agreement/grant.

(4) List key personnel who will work on the projects. Include title used in the work plans. In the appendix, include position descriptions and resumes for all key personnel. Position descriptions should clearly describe each position and duties, indicating desired qualifications and experience requirements related to the proposed projects. Resumes must indicate that the proposed staff member is qualified to carry out the proposed projects' activities. If a position is to be filled, indicate that information on the proposed position description.

(5) If personnel are to be only partially funded by this cooperative agreement, indicate the percentage of time to be allocated to the projects and identify the resources used to fund the remainder of the individual's salary.

E. Categorical Budget and Budget Justification (10 points)

This section should provide a clear estimate of the projects' program costs and justification for expenses for the entire cooperative agreement period. The budgets and budget justifications should be consistent with the tasks identified in the work plans.

(1) Provide a categorical budget for each of the 12-month budget periods requested for each of the four projects.

(2) If indirect costs are claimed, indicate and apply the current negotiated rate to the budget. Include a copy of the rate agreement in the appendix.

(3) Provide a narrative justification explaining why each line item is necessary/relevant to the proposed project. Include sufficient cost and other details to facilitate the determination of cost allowability (*i.e.,* equipment specifications, etc.).

Multi-Year Project Requirements (if applicable)

Projects requiring a second and/or third year must include a brief project narrative and budget (one additional page per year) addressing the developmental plans for each additional year of the project.

Additional Documents Must Be Uploaded as Appendix Items in *Grants.gov*

- Work plan, logic model and/or time line for proposed objectives.
- Position descriptions for key staff.
- Resumes of key staff that reflect current duties.
- Consultant or contractor proposed scope of work and letter of commitment (if applicable).
- Current Indirect Cost Agreement.
- Organizational chart.
- Map of area identifying project location(s).
- Additional documents to support narrative (*i.e.,* data tables, key news articles, etc.).

2. Review and Selection

Each application will be prescreened by the DGM staff for eligibility and completeness as outlined in the funding announcement. Applications that meet the eligibility criteria shall be reviewed for merit by the ORC based on evaluation criteria in this funding announcement. The ORC could be composed of both Tribal and Federal reviewers appointed by the IHS program to review and make recommendations on these applications. The technical review process ensures selection of quality projects in a national competition for limited funding. Incomplete applications and applications that are non-responsive to the eligibility criteria will not be referred to the ORC. The applicant will be notified via email of this decision by the Grants Management Officer of the DGM. Applicants will be notified by DGM, via email, to outline minor missing components (*i.e.,* budget narratives, audit documentation, key contact form) needed for an otherwise complete application. All missing documents must be sent to DGM on or before the due date listed in the email of notification of missing documents required.

To obtain a minimum score for funding by the ORC, applicants must address all program requirements and provide all required documentation.

VI. Award Administration Information

1. Award Notices

The Notice of Award (NoA) is a legally binding document signed by the Grants Management Officer and serves as the official notification of the grant award. The NoA will be initiated by the DGM in our grant system, GrantSolutions (*https://www.grantsolutions.gov*). Each entity that is approved for funding under this announcement will need to request or have a user account in GrantSolutions in order to retrieve their NoA. The NoA is the authorizing document for which funds are dispersed to the approved entities and reflects the amount of Federal funds awarded, the purpose of the grant, the terms and conditions of the award, the effective date of the award, and the budget/project period.

Disapproved Applicants

Applicants who received a score less than the recommended funding level for approval, 60 points, and were deemed to be disapproved by the ORC, will receive an Executive Summary Statement from the IHS program office within 30 days of the conclusion of the ORC outlining the strengths and weaknesses of their application submitted. The IHS program office will also provide additional contact information as needed to address questions and concerns as well as provide technical assistance if desired.

Approved But Unfunded Applicants

Approved but unfunded applicants that met the minimum scoring range and were deemed by the ORC to be "Approved," but were not funded due to lack of funding, will have their applications held by DGM for a period of one year. If additional funding becomes available during the course of FY 2016 the approved but unfunded application may be re-considered by the awarding program office for possible funding. The applicant will also receive an Executive Summary Statement from the IHS program office within 30 days of the conclusion of the ORC.

Note: Any correspondence other than the official NoA signed by an IHS grants management official announcing to the project director that an award has been made to their organization is not an authorization to implement their program on behalf of IHS.

2. Administrative Requirements

Cooperative agreements are administered in accordance with the following regulations, policies, and OMB cost principles:

A. The criteria as outlined in this Program Announcement.

B. Administrative Regulations for Grants:

- Uniform Administrative Requirements for HHS Awards, located at 45 CFR part 75.

C. Grants Policy:

- HHS Grants Policy Statement, Revised 01/07.

D. Cost Principles:

Uniform Administrative Requirements for HHS Awards, "Cost Principles," located at 45 CFR part 75, subpart E.

E. Audit Requirements:

- Uniform Administrative Requirements for HHS Awards, "Audit Requirements," located at 45 CFR part 75, subpart F.

3. Indirect Costs

This section applies to all grant recipients that request reimbursement of indirect costs (IDC) in their grant application. In accordance with HHS Grants Policy Statement, part II–27, IHS requires applicants to obtain a current IDC rate agreement prior to award. The rate agreement must be prepared in accordance with the applicable cost principles and guidance as provided by the cognizant agency or office. A current rate covers the applicable grant activities under the current award's budget period. If the current rate is not on file with the DGM at the time of award, the IDC portion of the budget will be restricted. The restrictions remain in place until the current rate is provided to the DGM.

Generally, IDC rates for IHS grantees are negotiated with the Division of Cost Allocation (DCA) *https://rates.psc.gov/* and the Department of Interior (Interior Business Center) *https://www.doi.gov/ibc/services/finance/indirect-Cost-Services/indian-tribes*. For questions regarding the indirect cost policy, please call the Grants Management Specialist listed under "Agency Contacts" or the main DGM office at (301) 443–5204.

4. Reporting Requirements

The grantee must submit required reports consistent with the applicable deadlines. Failure to submit required reports within the time allowed may result in suspension or termination of an active grant, withholding of additional awards for the project, or other enforcement actions such as withholding of payments or converting to the reimbursement method of payment. Continued failure to submit required reports may result in one or both of the following: (1) The imposition of special award provisions; and (2) the non-funding or non-award of other eligible projects or activities. This requirement applies whether the delinquency is attributable to the failure of the grantee organization or the individual responsible for preparation of the reports. Per DGM policy, all reports are required to be submitted electronically by attaching them as a "Grant Note" in GrantSolutions. Personnel responsible for submitting reports will be required to obtain a login and password for GrantSolutions. Please see the Agency Contacts list in section VII for the systems contact information.

The reporting requirements for this program are noted below.

A. Progress Reports

Program progress reports are required semi-annually within 30 days after the budget period ends. These reports must include a brief comparison of actual accomplishments to the goals established for the period, or, if applicable, provide sound justification for the lack of progress and other pertinent information as required. A final report must be submitted within 90 days of expiration of the budget/project period.

B. Financial Reports

Federal Financial Report FFR (SF–425), Cash Transaction Reports are due 30 days after the close of every calendar quarter to the Payment Management Services, HHS at: *http://www.dpm.psc.gov*. It is recommended that the applicant also send a copy of the FFR (SF–425) report to the Grants Management Specialist. Failure to submit timely reports may cause a disruption in timely payments to the organization.

Grantees are responsible and accountable for accurate information being reported on all required reports: The Progress Reports and Federal Financial Report.

C. Federal Sub-Award Reporting System (FSRS)

This award may be subject to the Transparency Act sub-award and executive compensation reporting requirements of 2 CFR part 170.

The Transparency Act requires the OMB to establish a single searchable database, accessible to the public, with information on financial assistance awards made by Federal agencies. The Transparency Act also includes a requirement for recipients of Federal grants to report information about first-tier sub-awards and executive compensation under Federal assistance awards.

IHS has implemented a Term of Award into all IHS Standard Terms and Conditions, NoAs and funding announcements regarding the FSRS reporting requirement. This IHS Term of Award is applicable to all IHS grant and cooperative agreements issued on or after October 1, 2010, with a $25,000 sub-award obligation dollar threshold met for any specific reporting period. Additionally, all new (discretionary) IHS awards (where the project period is made up of more than one budget period) and where: (1) The project period start date was October 1, 2010 or after and (2) the primary awardee will have a $25,000 sub-award obligation dollar threshold during any specific reporting period will be required to address the FSRS reporting. For the full IHS award term implementing this requirement and additional award applicability information, visit the DGM Grants Policy Web site at: *http://www.ihs.gov/dgm/policytopics/.*

D. Post Conference Grant Reporting

The following requirements were enacted in section 3003 of the Consolidated Continuing Appropriations Act, 2013, and Section 119 of the Continuing Appropriations Act, 2014; *Office of Management and Budget Memorandum M–12–12:* All HHS/IHS awards containing grants funds allocated for conferences will be required to complete a mandatory post award report for all conferences in excess of $20,000. Specifically: The total amount of funds provided in this grant/cooperative agreement that were spent for "Conference X," must be reported in final detailed actual costs *within 15 days of the completion of the conference.*

Final Post Conference Report should include all final expenditures on the cost categories as follows: (1) Contract/Planner, (2) Meeting Space/Venue, (3) Registration Web site, (4) Audio Visual, (5) Speakers Fees, (6) Federal Attendee Travel, (7) Non-Federal Attendee Travel, (8) Registration Fees, and (9) Other.

Failure to submit your required "Post Conference Report" within 15 days after the completion of the conference could result in cost associated with your conference being disallowed.

For additional questions please contact Ms. Michelle EagleHawk by telephone at (301) 443–1104 or email her at *Michelle.EagleHawk@ihs.gov.*

E. Compliance With Executive Order 13166 Implementation of Services Accessibility Provisions for All Grant Application Packages and Funding Opportunity Announcements

Recipients of federal financial assistance (FFA) from HHS must administer their programs in compliance with federal civil rights law. This means that recipients of HHS funds must ensure equal access to their programs without regard to a person's race, color, national origin, disability, age and, in some circumstances, sex and religion. This includes ensuring your programs are accessible to persons with limited English proficiency. HHS provides guidance to recipients of FFA on meeting their legal obligation to take reasonable steps to provide meaningful access to their programs by persons with limited English proficiency. Please see *http://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/guidance-federal-financial-assistance-recipients-title-VI/.*

The HHS Office for Civil Rights (OCR) also provides guidance on complying with civil rights laws enforced by HHS. Please see *http://www.hhs.gov/civil-rights/for-individuals/section-1557/index.html;* and *http://www.hhs.gov/civil-rights/index.html.* Recipients of FFA also have specific legal obligations for serving qualified individuals with disabilities. Please see *http://www.hhs.gov/civil-rights/for-individuals/disability/index.html.* Please contact the HHS OCR for more information about obligations and prohibitions under federal civil rights laws at *http://www.hhs.gov/civil-rights/for-individuals/disability/index.html* or call 1–800–368–1019 or TDD 1–800–537–7697. Also note it is an HHS Departmental goal to ensure access to quality, culturally competent care, including long-term services and supports, for vulnerable populations. For further guidance on providing culturally and linguistically appropriate services, recipients should review the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care at *http://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53.*

Pursuant to 45 CFR 80.3(d), an individual shall not be deemed subjected to discrimination by reason of his/her exclusion from benefits limited by federal law to individuals eligible for benefits and services from the IHS.

Recipients will be required to sign the HHS–690 Assurance of Compliance form which can be obtained from the following Web site: *http://www.hhs.gov/sites/default/files/forms/hhs-690.pdf,* and send it directly to the: U.S. Department of Health and Human Services, Office of Civil Rights, 200 Independence Ave. SW., Washington, DC 20201.

F. Federal Awardee Performance and Integrity Information System (FAPIIS)

The IHS is required to review and consider any information about the applicant that is in the Federal Awardee Performance and Integrity Information System (FAPIIS) before making any award in excess of the simplified acquisition threshold (currently $150,000) over the period of performance. An applicant may review and comment on any information about itself that a federal awarding agency previously entered. IHS will consider any comments by the applicant, in addition to other information in FAPIIS in making a judgment about the applicant's integrity, business ethics, and record of performance under federal awards when completing the review of risk posed by applicants as described in 45 CFR 75.205.

As required by 45 CFR part 75 Appendix XII of the Uniform Guidance, non-Federal entities (NFEs) are required to disclose in FAPIIS any information about criminal, civil, and administrative proceedings, and/or affirm that there is no new information to provide. This applies to NFEs that receive federal awards (currently active grants, cooperative agreements, and procurement contracts) greater than $10,000,000 for any period of time during the period of performance of an award/project.

Mandatory Disclosure Requirements

As required by 2 CFR part 200 of the Uniform Guidance, and the HHS implementing regulations at 45 CFR part 75, effective January 1, 2016, the IHS must require a non-Federal entity or an applicant for a federal award to disclose, in a timely manner, in writing to the IHS or pass-through entity all violations of federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the federal award.

Submission is required for all applicants and recipients, in writing, to the IHS and to the HHS Office of Inspector General all information related to violations of Federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the Federal award. 45 CFR 75.113.

Disclosures must be sent in writing to: U.S. Department of Health and Human Services, Indian Health Service, Division of Grants Management, ATTN: Robert Tarwater, Director, 5600 Fishers Lane, Mailstop 09E70, Rockville, Maryland 20857. (Include "Mandatory Grant Disclosures" in subject line). Ofc: (301) 443–5204, Fax: (301) 594–0899, email: *Robert.Tarwater@ihs.gov*; and

U.S. Department of Health and Human Services, Office of Inspector General, ATTN: Mandatory Grant Disclosures, Intake Coordinator, 330 Independence Avenue SW., Cohen Building, Room 5527, Washington, DC 20201, URL: *http://oig.hhs.gov/fraud/*

reportfraud/index.asp. (Include "Mandatory Grant Disclosures" in subject line). Fax: (202) 205–0604. (Include "Mandatory Grant Disclosures" in subject line) or email: *MandatoryGranteeDisclosures@oig.hhs.gov.*

Failure to make required disclosures can result in any of the remedies described in 45 CFR 75.371. Remedies for noncompliance, including suspension or debarment (See 2 CFR parts 180 and 376 and 31 U.S.C. 3321).

VII. Agency Contacts

1. Questions on the programmatic issues may be directed to: Ms. Michelle EagleHawk, Deputy Director, ODSCT, Mail Stop: 8E17, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone: (301) 443–1104, email: *Michelle.EagleHawk@ihs.gov.*

2. Questions on grants management and fiscal matters may be directed to: Ms. Patience Musikikongo, Grants Management Specialist, Division of Grants Management, Mail Stop: 09E70, 5600 Fishers Lane, Rockville, MD 20857, Telephone: (301) 443–2059, Fax: (301) 594–0899, email: *Patience.Musikikongo@ihs.gov.*

3. Questions on systems matters may be directed to: Mr. Paul Gettys, Grant Systems Coordinator, Division of Grants Management, Mail Stop: 09E70, 5600 Fishers Lane, Rockville, MD 20857, Phone: (301) 443–2114; or the DGM main line (301) 443–5204, Fax: (301) 594–0899, email: *Paul.Gettys@ihs.gov.*

VIII. Other Information

The Public Health Service strongly encourages all cooperative agreement and contract recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. In addition, Public Law 103–227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of the facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the HHS mission to protect and advance the physical and mental health of the American people.

Dated: July 7, 2016.

Elizabeth A. Fowler,

Deputy Director for Management Operations Indian Health Service.

[FR Doc. 2016–16824 Filed 7–14–16; 8:45 am]

BILLING CODE 4160–16–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Office of Direct Service and Contracting Tribes; National Indian Health Outreach and Education II

Announcement Type: New/Competing Continuation.

Announcement Number: HHS–2016–IHS–NIHOE–2–BH–HIV/AIDS–0001.

Catalog of Federal Domestic Assistance Number: 93.933.

Key Dates

Application Deadline Date: August 15, 2016.

Review Date: August 22, 2016.

Earliest Anticipated Start Date: September 15, 2016.

Proof of Non-Profit Status Due Date: August 15, 2016.

I. Funding Opportunity Description

Statutory Authority

The Indian Health Service (IHS) is accepting competitive applications for two limited competition cooperative agreements under the National Indian Health Outreach and Education (NIHOE–II) program: The Behavioral Health (BH)—to include the Substance Abuse and Suicide Prevention (SASP) program, formerly known as the Methamphetamine and Suicide Prevention Intervention, and the Domestic Violence Prevention (DVP) program, formerly known as the Domestic Violence Prevention Initiative—national awareness, visibility, advocacy, outreach and education award and the Human Immunodeficiency Virus/Acquired Immune Deficiency Syndrome (HIV/AIDS) outreach and education award. The BH national awareness, visibility, advocacy, and education award is funded by IHS and is authorized under the Snyder Act, codified at 25 U.S.C. 13; the Transfer Act, codified at 42 U.S.C. 2001; the Consolidated Appropriations Act, 2016, Public Law 114–113. The HIV/AIDS outreach and education award is funded by the Office of the Secretary (OS), Department of Health and Human Services (HHS). Funding for the HIV/AIDS award will be provided by OS via an Intra-Departmental Delegation of Authority dated May 1st, 2016 to IHS to permit obligation of funding appropriated by the Consolidated Appropriations Act, 2016, Public Law 114–113. Each award is funded through a separate funding stream by each respective Agency's appropriations. The awardee is responsible for accounting for each of the two awards separately and must provide two separate financial reports per year of funding (one for each award), as indicated below. This program is described in the Catalog of Federal Domestic Assistance under 93.933.

Background

The NIHOE program carries out health program objectives in the American Indian/Alaska Native (AI/AN) community in the interest of improving Indian health care for all 567 Federally-recognized Tribes including Tribal governments operating their own health care delivery systems through Indian Self-Determination and Education Assistance Act (ISDEAA) contracts and compacts with the IHS and Tribes that continue to receive health care directly from the IHS. This program addresses health policy and health programs issues and disseminates educational information to all AI/AN Tribes and villages. The NIHOE II BH and HIV/AIDS awards require that public forums be held at Tribal educational consumer conferences to disseminate changes and updates in the latest health care information. These awards also require that regional and national meetings be coordinated for information dissemination as well as for the inclusion of planning and technical assistance and health care recommendations on behalf of participating Tribes to ultimately inform IHS and the HHS based on Tribal input through a broad based consumer network.

Purpose

The purpose of these cooperative agreements is to further IHS health program objectives in the AI/AN community with awareness, visibility, advocacy, and education efforts for the BH and HIV/AIDS programs on a national scale and in the interest of improving Indian health care. This announcement includes two separate awards, each of which will be awarded as noted below. The purpose of the BH award is to promote behavioral health as central to the health and well-being of AI/AN communities.

The purpose of the HIV/AIDS award is to further the goals of the national HIV/AIDS program. HIV and AIDS are a critical and growing health issue within the AI/AN population. The IHS National HIV/AIDS Program seeks to avoid complacency and to increase awareness of the impact of HIV/AIDS on AI/ANs. All activities are part of the IHS's implementation plan to meet the three goals of the President's National HIV/AIDS Strategy (NHAS) to reduce the number of people who become infected with HIV, increase access to care and optimize health outcomes for people living with HIV, and reduce HIV-related disparities. This population faces additional health disparities that contribute significantly to the risk of HIV transmission such as substance abuse and sexually transmitted infections. Amongst AI/AN people, HIV/AIDS exists in both urban and rural populations (and on or near Tribal lands); however, many of those living with HIV are not aware of their status. These statistics, risk factors, and missed opportunities for screening illuminate the need to go beyond raising awareness about HIV and begin active integration of initiatives that will help routinize HIV services. If the status quo is unchanged, prevalence will continue to increase and AI/AN communities may face an irreversible problem. Therefore, the National HIV/AIDS Program is working to change the way HIV is discussed, to change and improve the way HIV testing is integrated into health services, and to firmly establish linkages and access to care. The IHS HIV/AIDS Program is implemented and executed via an integrated and comprehensive approach through collaborations across multi-health sectors, both internal and external to the agency. It attempts to encompass all types of service delivery 'systems' including IHS/Tribal/Urban facilities. The IHS HIV/AIDS Program is committed to realizing the goals of the President's NHAS and has bridged the objectives and implementation to the IHS HIV/AIDS Strategic Plan.

Limited Competition Justification

Competition for both of the awards included in this announcement is limited to national Indian health care organizations with at least ten years of experience providing national awareness, visibility, advocacy, education and outreach on a national scale. This limitation ensures that the awardee will have: (1) A national information-sharing infrastructure which will facilitate the timely exchange of information between HHS and Tribes and Tribal organizations on a broad scale; (2) a national perspective on the needs of AI/AN communities that will ensure that the information developed and disseminated through the projects is appropriate, useful and addresses the most pressing needs of AI/AN communities; and (3) established relationships with Tribes and Tribal organizations that will foster open and honest participation by AI/AN communities. Regional or local organizations will not have the mechanisms in place to conduct communication on a national level, nor will they have an accurate picture of the health care needs facing AI/ANs nationwide. Organizations with less experience will lack the established relationships with Tribes and Tribal organizations throughout the country that will facilitate participation and the open and honest exchange of information between Tribes and HHS. With the limited funds available for these projects, HHS must ensure that the education and outreach efforts described in this announcement reach the widest audience possible in a timely fashion, are appropriately tailored to the needs of AI/AN communities throughout the country, and come from a source that AI/ANs recognize and trust. For these reasons, this is a limited competition announcement.

II. Award Information

Type of Award

Cooperative Agreement.

Estimated Funds Available

The total amount of funding identified for the current funding period covering fiscal year (FY) 2016–2018 is approximately $1,200,000 (*i.e.,* $400,000 to fund two cooperative agreements per year); $300,000 will be awarded for the BH award and $100,000 will be awarded for the HIV/AIDS award. The amount of funding available for competing and continuation awards issued under this announcement is subject to the availability of appropriations and budgetary priorities of the Agency. The IHS is under no obligation to make awards that are selected for funding under this announcement.

Anticipated Number of Awards

Two awards will be issued under this program announcement. It is the intention of IHS and the OS that one entity will receive both awards. OS and IHS will concur on the final decision as to who will receive both awards.

Project Period

The project periods for each award will be for three consecutive years and will run from September 15, 2016 with completion by September 14, 2019.

Cooperative Agreement

Cooperative agreements awarded by the HHS are administered under the same policies as a grant. The funding agency (IHS and OS) is required to have substantial programmatic involvement in the project during the entire award segment. Below is a detailed description of the level of involvement required for both IHS, acting on behalf of the OS for the HIV/AIDS award, and the grantee. IHS will be responsible for activities listed under section A and the grantee will be responsible for activities listed under section B as stated:

Substantial Involvement Description for Cooperative Agreement

A. IHS Programmatic Involvement

The IHS assigned program official will monitor the overall progress of the awardee's execution of the requirements of the two awards: IHS award and OS award noted below as well as their adherence to the terms and conditions of the cooperative agreements. This includes providing guidance for required reports, developing of tools, and other products, interpreting program findings, and assisting with evaluations and overcoming any difficulties or performance issues encountered. The IHS assigned program official must approve all presentations, electronic content, and other materials, including mass emails, developed by awardee pursuant to these awards and any supplemental awards prior to the presentation or dissemination of such materials to any party.

(1) Behavioral Health award:

i. The IHS assigned program official will work in partnership with the awardee to elevate the priority of behavioral health by coordinating in-person and virtual meetings of the National Tribal Advisory Committee on Behavioral Health and represent the National Indian Health Board on Action Alliance for Suicide Prevention's AI/AN Task Force to assist in national awareness, visibility, and advocacy to promote behavioral health and wellness.

ii. The IHS assigned program official will work in partnership with the awardee to promote a national premier AI/AN behavioral health conference, to include a SASP grantee, and DVP grantee meeting with the ultimate goal of reducing the outstanding behavioral health disparities among AI/AN people.

(2) HIV/AIDS award:

IHS staff will provide support for the HIV/AIDS award as follows:

i. The IHS assigned program official will work in partnership with the awardee in all decisions involving strategy, hiring of grantee personnel, deployment of resources, release of public information materials, quality assurance, coordination of activities, training, reports, budgets, and evaluations. Collaboration includes data analysis, interpretation of findings, and reporting.

ii. The IHS assigned program official will work closely with OS and all participating IHS health services/programs, as appropriate, to coordinate award activities.

iii. The IHS assigned program official will coordinate the following for OS and the participating IHS program offices and staff:

- Discussion and release of any and all special grant conditions upon fulfillment.
- Monthly scheduled conference calls.
- Appropriate dissemination of required reports to each participating program.

iv. The IHS will, jointly with the awardee, plan and set an agenda for each of the conferences mentioned in this announcement that:

- Shares the training and/or accomplishments.
- Fosters collaboration amongst the participating program offices, agencies, and/or departments.
- Increases visibility for the partnership between the awardee and the IHS and OS.

v. IHS will provide guidance in addressing deliverables and requirements.

vi. IHS will provide guidance in preparing articles for publication and/or presentations of program successes, lessons learned, and new findings.

vii. IHS will communicate via monthly conference calls, individual or collective site visits, and monthly meetings.

viii. IHS staff will review articles concerning the HHS, OS, and the Agency for accuracy and may, as requested by the awardee, provide relevant articles.

ix. IHS will provide technical assistance to the entity as requested.

x. IHS staff may, at the request of the entity's board, participate on study groups and may recommend topics for analysis and discussion.

B. Grantee Cooperative Agreement Award Activities

The awardee must comply with relevant Office of Management and Budget (OMB) Circular provisions regarding lobbying, any applicable lobbying restrictions provided under other law and any applicable restriction on the use of appropriated funds for lobbying activities.

The awardee is responsible for the following in addition to fulfilling all requirements noted for each award component: BH and HIV/AIDS.

i. To succinctly and independently address the requirements for each of the two awards listed below: BH and HIV/AIDS.

ii. To facilitate a forum or forums at which concerns can be heard that are representative of all Tribal governments in the area of health care policy analysis and program development for each of the two components listed above.

iii. To assure that health care outreach and education is based on Tribal input through a broad-based consumer network involving the Area Indian health boards or health board representatives from each of the 12 IHS Areas.

iv. To establish relationships with other national Indian organizations, professional groups, and Federal, State, and local entities supportive of AI/AN health programs.

v. To improve and expand access for AI/AN Tribal governments to all available programs within the HHS.

vi. To disseminate timely health care information to Tribal governments, AI/AN health boards, other national Indian organizations, professional groups, Federal, State, and local entities.

vii. To provide periodic dissemination of health care information, including publication of a newsletter four times a year that features articles on BH, SASP, DVP, and HIV/AIDS health promotion/disease/prevention activities and models of best or promising practices, health policy, and funding information relevant to AI/AN, etc.

SUMMARY OF TASKS TO BE PERFORMED

BH:

In alignment with the above program and independent from HIV/AIDS activities (both via fiscal resources and programmatic implementation), the awardee shall:

- Facilitate and host an annual in-person meeting and virtual meeting of the National Tribal Advisory Committee on Behavioral Health.
- Provide leadership for the National Action Alliance for Suicide Prevention's American Indian/Alaska Native Task Force.
- Host and promote, in partnership with program official, a national premier AI/AN conference on current and pressing Behavioral Health topics, including meetings of the SASP and DVP grantees, provide workshops, pre-conference institutes, and/or presentations including, but not limited to, suicide, substance use, domestic violence, sexual assault, mental health illness, wellness, promising practices, and/or best practices of Tribal BH programs (venue location, theme and content of presentations to be agreed upon by the awardee and the IHS assigned program official).
- Increase capacity at the tribal level on grant writing to increase the likelihood of awards from various Federal agencies.
- Develop, maintain, and disseminate comprehensive information on tribal BH programs, curricula, findings, articles, and strategies to all Tribal BH programs.

HIV/AIDS:

In alignment with the above program and independent from BH activities (both via fiscal resources and programmatic implementation), the awardee shall:

- Disseminate existing HIV/AIDS messages to AI/AN audiences in a format designed to solicit, collect, and report on community-level feedback and generate discussion regarding the disease and its prevention. This may include electronic and emerging means of communication. At least four distinct audiences (such as women, young people, etc.) will be addressed and engaged. Preference will be given to reaching audiences with the highest HIV burden or potential increases as supported by the NHAS.
- Disseminate existing IHS HIV/AIDS program and other HIV/AIDS training materials to educators, health care providers, and other key audiences. Collect and report on relevant evaluation criteria, including impacts on underlying knowledge, attitudes, or beliefs about HIV acquisition, testing, or treatment.
- Deliver HIV/AIDS technical assistance and activity support program. Engage in documented partnerships with AI/AN communities to expand their capacity relevant to HIV/AIDS education and prevention efforts. Local activity support may include sub-awards of resources and distribution of incentives to qualified AI/AN-serving community organizations increasing HIV/AIDS education and prevention in their populations. Sub-award eligibility standards and management controls will be proposed by the awardee and will be subject to IHS approval. These activities must be conducted in accordance with Federal grant policies and procedures. Awardee will collect and maintain relevant evaluation materials and generate reports that highlight progress towards the President's NHAS goals on the community level and that collect best practices for dissemination to other communities.
- Contribute technical expertise to the IHS HIV/AIDS program and develop formal written documents responding to information requests from the public regarding HIV/AIDS initiatives.
- Develop and launch anti-stigma messaging for at least one audience, coordinated with other local activities to increase HIV screening and increase access to services, or increase positive role modeling for people living with, or at risk of, acquiring HIV/AIDS.

- Support and document issue-specific discussions with Tribal Leaders as needed to address effective prevention interventions for AI/AN populations as noted in the President's NHAS.
- Obtain approval from the IHS assigned program official of all presentations, electronic content, and other materials, including mass emails, developed by awardee pursuant to this award and any supplemental awards prior to the presentation or dissemination of such materials to any party, allowing for a reasonable amount of time for IHS review.

III. Eligibility Information

I.

1. Eligibility

To be eligible for this "New/Competing Continuation Announcement", an applicant must:

Provide proof of non-profit status with the application, *e.g.* 501(c)(3).

Be a national Indian health care organizations with at least ten years of experience providing national awareness, visibility, advocacy, education and outreach on a national scale to ensure:

(1) A national information-sharing infrastructure which will facilitate the timely exchange of information between HHS and Tribes and Tribal organizations on a broad scale with the infrastructure in place to accomplish the work under the proposed program;

(2) A national perspective on the needs of AI/AN communities that will ensure that the information developed and disseminated through the projects is appropriate, useful and addresses the most pressing needs of AI/AN communities; and,

(3) Established relationships with Tribes and Tribal organizations that will foster open and honest participation by AI/AN communities.

Organizations with less experience will lack the established relationships with Tribes and Tribal organizations throughout the country to facilitate participation and the open and honest exchange of information between Tribes and HHS.

Demonstrate expertise in the following areas:

- Representing all Tribal governments and providing a variety of services to Tribes, Area health boards, Tribal organizations, and Federal agencies, and playing a major role in focusing attention on Indian health care needs, resulting in improved health outcomes for AI/ANs.
- Promotion and support of Indian education and coordinating efforts to inform AI/AN of Federal decisions that affect Tribal government interests including the improvement of Indian health care.
- National health policy and health programs administration.
- Have a national AI/AN constituency and clearly support critical services and activities within the IHS mission of improving the quality of health care for AI/AN people.
- Portray evidence of their solid support of improved health care in Indian Country.
- Provide evidence of at least ten years of experience providing education and outreach on a national scale.

Regional and or local organizations that do not have mechanisms in place to conduct communication on a national level to meet the health care needs facing AI/ANs nationwide as outlined in this funding announcement will not be considered eligible.

With the limited funds available for these projects, HHS must ensure that the education and outreach efforts described in this announcement reach the widest audience possible in a timely fashion; are appropriately tailored to the needs of AI/AN communities throughout the country, and come from a source that AI/ANs recognize and trust.

Note: Please refer to Section IV.2 (Application and Submission Information/Subsection 2, Content and Form of Application Submission) for additional proof of applicant status documents required such as Tribal resolutions, proof of non-profit status, etc.

2. Cost Sharing or Matching

The IHS does not require matching funds or cost sharing for grants or cooperative agreements.

3. Other Requirements

If application budgets exceed the highest dollar amount outlined under the "Estimated Funds Available" section within this funding announcement, the application will be considered ineligible and will not be reviewed for further consideration. If deemed ineligible, IHS will not return the application. The applicant will be notified by email by the Division of Grants Management (DGM) of this decision.

Proof of Non-Profit Status

Organizations claiming non-profit status must submit proof. A copy of the 501(c)(3) Certificate must be received with the application submission by the Application Deadline Date listed under the Key Dates section on page one of this announcement.

An applicant submitting any of the above additional documentation after the initial application submission due date is required to ensure the information was received by the IHS by obtaining documentation confirming delivery (*i.e.,* FedEx tracking, postal return receipt, etc.).

IV. Application and Submission Information

1. Obtaining Application Materials

The application package and detailed instructions for this announcement can be found at *http://www.Grants.gov* or *http://www.ihs.gov/dgm/funding/.*

Questions regarding the electronic application process may be directed to Mr. Paul Gettys at (301) 443–2114 or (301) 443–5204.

2. Content and Form Application Submission

Two complete separate signed applications are required. Both applications should address all the following components separately in each application. Each separate application must include the project narrative as an attachment to the application package. Mandatory documents for all applicants include:

- Table of contents.
- Abstract (one page) summarizing the project.
- Application forms:
  - ○ SF–424, Application for Federal Assistance.
  - ○ SF–424A, Budget Information—Non-Construction Programs.
  - ○ SF–424B, Assurances—Non-Construction Programs.
- Budget Justification and Narrative (must be single spaced and not exceed five pages).
- Project Narrative (must be single spaced and not exceed 20 pages).
  - ○ Background information on the organization.
  - ○ Proposed scope of work, objectives, and activities that provide a description of what will be accomplished, including a one-page Timeframe Chart.
- Letter of Support from Organization's Board of Directors.
- 501(c)(3) Certificate (if applicable).
- Position Descriptions for all key personnel.
- Contractor/Consultant resumes or qualifications and scope of work.
- Disclosure of Lobbying Activities (SF–LLL).
- Certification Regarding Lobbying (GG–Lobbying Form).
- Copy of current Negotiated Indirect Cost (IDC) rate agreement (required) in order to receive IDC.
- Organizational Chart (optional).

- Documentation of current Office of Management and Budget (OMB) 45 CFR part 75 or other required Financial Audit (if applicable). Acceptable forms of documentation include:
  - ○ Email confirmation from Federal Audit Clearinghouse (FAC) that audits were submitted; or
  - ○ Face sheets from audit reports. These can be found on the FAC Web site: *http://harvester.census.gov/sac/dissem/accessoptions.html?submit=Go+To+Database*

Public Policy Requirements

All Federal-wide public policies apply to IHS grants and cooperative agreements with exception of the Discrimination policy.

Requirements for Project and Budget Narratives

A. Project Narrative: This narrative should be a separate Word document that is no longer than 20 pages and must: Be single-spaced, be type written, have consecutively numbered pages, use black type not smaller than 12 characters per one inch, and be printed on one side only of standard size 8½″ x 11″ paper.

Be sure to succinctly address and answer all questions listed under the narrative and place them under the evaluation criteria (refer to Section V.1, Evaluation criteria in this announcement) and place all responses and required information in the correct section (noted below), or they shall not be considered or scored. These narratives will assist the Objective Review Committee (ORC) in becoming familiar with the applicant's activities and accomplishments prior to this cooperative agreement award. If the narrative exceeds the page limit, only the first 20 pages will be reviewed. The 20-page limit for the narrative does not include the work plan, standard forms, Tribal resolutions, table of contents, budget, budget justifications, narratives, and/or other appendix items.

There are three parts to the narrative: Part A—Program Information; Part B—Program Planning and Evaluation; and Part C—Program Report. See below for additional details about what must be included in the narrative.

Reminder: You are required to submit two separate complete and signed application packages. One for the BH cooperative agreement and one complete signed application package for the HIV/AIDS cooperative agreement. This applies to the narratives and budgets as well and all components listed below. Be sure to address each component separately in its respective application package. The page limitations below are for each narrative and budget submitted.

Part A: Program Information (8 Page Limitation)

Section 1: Needs.

Describe how the national Indian organization has the experience to provide outreach and education efforts regarding the pertinent changes and updates in health care for each of the two components listed herein: BH and HIV/AIDS.

Part B: Program Planning and Evaluation (7 Page Limitation)

Section 1: Program Plans.

Describe fully and clearly how the national Indian organization plans to address the NIHOE II BH and HIV/AIDS requirements, including how the national Indian organization plans to demonstrate improved health education and outreach services to all 567 Federally-recognized Tribes for each of the two components described herein.

Section 2: Program Evaluation.

Describe fully and clearly how the outreach and education efforts will impact changes in knowledge and awareness in Tribal communities regarding both components. Identify anticipated or expected benefits for the Tribal constituency.

Part C: Program Report (5 Page Limitation)

Section 1: Describe major accomplishments over the last 24 months.

Identify and describe significant program achievements associated with the delivery of quality health outreach and education. Provide a comparison of the actual accomplishments to the goals established for the project period for both components, or if applicable, provide justification for the lack of progress.

Section 2: Describe major activities over the last 24 months.

Identify and summarize recent major health related outreach and education project activities of the work performed for both components during the last project period.

B. Budget Narrative: This narrative must include a line item budget with a narrative justification for all expenditures identifying reasonable and allowable costs necessary to accomplish the goals and objectives as outlined in the project narrative. Budget should match the scope of work described in the project narrative. The budget narrative should not exceed five pages.

3. Submission Dates and Times

Applications must be submitted electronically through *Grants.gov* by 11:59 p.m. Eastern Daylight Time (EDT) on the Application Deadline Date listed in the Key Dates section on page one of this announcement. Any application received after the application deadline will not be accepted for processing, nor will it be given further consideration for funding. *Grants.gov* will notify the applicant via email if the application is rejected.

If technical challenges arise and assistance is required with the electronic application process, contact *Grants.gov* Customer Support via email to *support@grants.gov* or at (800) 518–4726. Customer Support is available to address questions 24 hours a day, 7 days a week (except on Federal holidays). If problems persist, contact Mr. Paul Gettys (*Paul.Gettys@ihs.gov*), DGM Grant Systems Coordinator, by telephone at (301) 443–2114 or (301) 443–5204. Please be sure to contact Mr. Gettys at least ten days prior to the application deadline. Please do not contact the DGM until you have received a *Grants.gov* tracking number. In the event you are not able to obtain a tracking number, call the DGM as soon as possible.

If the applicant needs to submit a paper application instead of submitting electronically through *Grants.gov,* a waiver must be requested. Prior approval must be requested and obtained from Mr. Robert Tarwater, Director, DGM, (see Section IV.6 below for additional information). The waiver must: (1) Be documented in writing (emails are acceptable), *before* submitting a paper application, and (2) include clear justification for the need to deviate from the required electronic grants submission process. A written waiver request must be sent to *GrantsPolicy@ihs.gov* with a copy to *Robert.Tarwater@ihs.gov.* Once the waiver request has been approved, the applicant will receive a confirmation of approval email containing submission instructions and the mailing address to submit the application. A copy of the written approval *must* be submitted along with the hardcopy of the application that is mailed to DGM. Paper applications that are submitted without a copy of the signed waiver from the Senior Policy Analyst of the DGM will not be reviewed or considered for funding. The applicant will be notified via email of this decision by the Grants Management Officer of the DGM. Paper applications must be received by the DGM no later than 5 p.m., EDT, on the Application Deadline Date listed in the Key Dates section on page one of this announcement. Late applications will not be accepted for processing or considered for funding.

4. Intergovernmental Review

Executive Order 12372 requiring intergovernmental review is not applicable to this program.

5. Funding Restrictions

- Pre-award costs are not allowable.
- The available funds are inclusive of direct and appropriate indirect costs.
- Only one grant/cooperative agreement will be awarded per component.
- IHS will not acknowledge receipt of applications.

6. Electronic Submission Requirements

All applications must be submitted electronically. Please use the *http://www.Grants.gov* Web site to submit an application electronically and select the "Find Grant Opportunities" link on the homepage. Download a copy of the application package, complete it offline, and then upload and submit the completed application via the *http://www.Grants.gov* Web site. Electronic copies of the application may not be submitted as attachments to email messages addressed to IHS employees or offices.

If the applicant receives a waiver to submit paper application documents, they must follow the rules and timelines that are noted below. The applicant must seek assistance at least ten days prior to the Application Deadline Date listed in the Key Dates section on page one of this announcement.

Applicants that do not adhere to the timelines for System for Award Management (SAM) and/or *http://www.Grants.gov* registration or that fail to request timely assistance with technical issues will not be considered for a waiver to submit a paper application.

Please be aware of the following:

- Please search for the application package in *http://www.Grants.gov* by entering the CFDA number or the Funding Opportunity Number. Both numbers are located in the header of this announcement.
- If you experience technical challenges while submitting your application electronically, please contact *Grants.gov* Support directly at: *support@grants.gov* or (800) 518–4726. Customer Support is available to address questions 24 hours a day, 7 days a week (except on Federal holidays).
- Upon contacting *Grants.gov*, obtain a tracking number as proof of contact. The tracking number is helpful if there are technical issues that cannot be resolved and a waiver from the agency must be obtained.
- If it is determined that a waiver is needed, the applicant must submit a request in writing (emails are acceptable) to *GrantsPolicy@ihs.gov* with a copy to *Robert.Tarwater@ihs.gov*. Please include a clear justification for the need to deviate from the standard electronic submission process.
- If the waiver is approved, the application should be sent directly to the DGM by the Application Deadline Date listed in the Key Dates section on page one of this announcement.
- Applicants are strongly encouraged not to wait until the deadline date to begin the application process through *Grants.gov* as the registration process for SAM and *Grants.gov* could take up to fifteen working days.
- Please use the optional attachment feature in *Grants.gov* to attach additional documentation that may be requested by the DGM.
- All applicants must comply with any page limitation requirements described in this Funding Announcement.
- After electronically submitting the application, the applicant will receive an automatic acknowledgment from *Grants.gov* that contains a *Grants.gov* tracking number. The DGM will download the application from *Grants.gov* and provide necessary copies to the appropriate agency officials. Neither the DGM nor the Office of Direct Service and Contracting Tribes will notify the applicant that the application has been received.
- Email applications will not be accepted under this announcement.

Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS)

All IHS applicants and grantee organizations are required to obtain a DUNS number and maintain an active registration in the SAM database. The DUNS number is a unique 9-digit identification number provided by D&B which uniquely identifies each entity. The DUNS number is site specific; therefore, each distinct performance site may be assigned a DUNS number. Obtaining a DUNS number is easy, and there is no charge. To obtain a DUNS number, please access it through *http://fedgov.dnb.com/webform*, or to expedite the process, call (866) 705–5711.

All HHS recipients are required by the Federal Funding Accountability and Transparency Act of 2006, as amended ("Transparency Act"), to report information on sub-awards. Accordingly, all IHS grantees must notify potential first-tier sub-recipients that no entity may receive a first-tier sub-award unless the entity has provided its DUNS number to the prime grantee organization. This requirement ensures the use of a universal identifier to enhance the quality of information available to the public pursuant to the Transparency Act.

System for Award Management (SAM)

Organizations that were not registered with Central Contractor Registration (CCR) and have not registered with SAM will need to obtain a DUNS number first and then access the SAM online registration through the SAM home page at *https://www.sam.gov* (U.S. organizations will also need to provide an Employer Identification Number from the Internal Revenue Service that may take an additional 2–5 weeks to become active). Completing and submitting the registration takes approximately one hour to complete and SAM registration will take 3–5 business days to process. Registration with the SAM is free of charge. Applicants may register online at *https://www.sam.gov*.

Additional information on implementing the Transparency Act, including the specific requirements for DUNS and SAM, can be found on the IHS Grants Management, Grants Policy Web site: *http://www.ihs.gov/dgm/policytopics/*.

V. Application Review Information

The instructions for preparing the application narrative also constitute the evaluation criteria for reviewing and scoring the application. Weights assigned to each section are noted in parentheses. The 20-page narrative should include only the first year of activities; information for multi-year projects should be included as an appendix. See "Multi-year Project Requirements" at the end of this section for more information. The narrative section should be written in a manner that is clear to outside reviewers unfamiliar with prior related activities of the applicant. It should be well organized, succinct, and contain all information necessary for reviewers to understand the project fully. Points will be assigned to each evaluation criteria adding up to a total of 100 points. A minimum score of 60 points is required for funding. Points are assigned as follows:

1. Criteria

A. Introduction and Need for Assistance (15 Points)

(1) Describe the organization's current health, education and technical assistance operations as related to the broad spectrum of health needs of the AI/AN community. Include what programs and services are currently provided (*i.e.*, Federally-funded, State-funded, etc.), and identify any

memorandums of agreement with other national, Area or local Indian health board organizations. This could also include HHS agencies that rely on the applicant as the primary gateway organization that is capable of providing the dissemination of health information to Tribes. Include information regarding technologies currently used (*i.e.,* hardware, software, services, Web sites, etc.), and identify the source(s) of technical support for those technologies (*i.e.,* in-house staff, contractors, vendors, etc.). Include information regarding how long the applicant has been operating and its length of association/partnerships with Area health boards, etc. [historical collaboration].

(2) Describe the organization's current technical assistance ability. Include what programs and services are currently provided, programs and services projected to be provided, and describe any memorandums of agreement with other national Indian organizations that deem the applicant as the primary source of health policy information for AI/ANs, or any other memorandums of agreement with other Area Indian health boards, etc.

(3) Describe the population to be served by the proposed projects. Are they hard to reach? Are there barriers? Include a description of the number of Tribes who currently benefit from the technical assistance provided by the applicant.

(4) Describe the geographic location of the proposed project including any geographic barriers experienced by the recipients of the technical assistance to the health care information provided.

(5) Identify all previous IHS cooperative agreement awards received, dates of funding and summaries of the projects' accomplishments. State how previous cooperative agreement funds facilitated education, training and technical assistance nationwide for AI/ANs. (Copies of reports will not be accepted.)

(6) Describe collaborative and supportive efforts with national, Area, and local Indian health boards.

(7) Explain the need/reason for the proposed projects by identifying specific gaps or weaknesses in services or infrastructure that will be addressed by the proposed projects. Explain how these gaps/weaknesses have been assessed.

(8) Explain what measures were taken or will be taken to ensure the proposed projects will not create new gaps or weaknesses in services or infrastructure.

(9) Describe the effect of the proposed project on current programs (*i.e.,* Federally-funded, State funded, etc.) and, if applicable, on current equipment (*i.e.,* hardware, software, services, etc.). Include the effect of the proposed projects on planned/anticipated programs and/or equipment.

(10) Describe how the projects relate to the purpose of the cooperative agreement by identifying how the proposed project will address national Indian health care outreach and education regarding various health data listed, *e.g.,* BH and HIV and AIDS, dissemination, training, and technical assistance, etc.

B. Project Objective(s), Work Plan and Approach (40 Points)

(1) Identify the proposed project objective(s) for each of the two projects, as applicable, addressing the following:

- Measurable and (if applicable) quantifiable.
- results oriented.
- time-limited.

Example: Issue four quarterly newsletters, provide alerts and quantify number of contacts with Tribes. Goals must be clear and concise.

(2) Address how the proposed projects will result in change or improvement in program operations or processes for each proposed project objective for the selected projects. Also address what tangible products, if any, are expected from the project, (*i.e.,* legislative analysis, policy analysis, annual conferences, mid-year conferences, summits, etc.).

(3) Address the extent to which the proposed projects will provide, improve, or expand services that address the need(s) of the target population. Include a strategic plan and business plan currently in place that are being used that will include the expanded services. Include the plan(s) with the application submission.

(4) Submit a work plan in the Appendix that:

- Provides the action steps on a timeline for accomplishing each of the projects' proposed objective(s).
- Identifies who will perform the action steps.
- Identifies who will supervise the action steps taken.
- Identifies what tangible products will be produced during and at the end of the proposed project objective(s).
- Identifies who will accept and/or approve work products during the duration of the proposed projects and at the end of the proposed projects.
- Identifies any training that will take place during the proposed projects and who will be attending the training.
- Identifies evaluation activities proposed in the work plans.

(5) If consultants or contractors will be used during the proposed project, please include the following information in their scope of work (or note if consultants/contractors will not be used):

- Educational requirements.
- Desired qualifications and work experience.
- Expected work products to be delivered on a timeline.

If a potential consultant/contractor has already been identified, please include a resume in the Appendix.

(6) Describe what updates will be required for the continued success of the proposed project. Include when these updates are anticipated and where funds will come from to conduct the update and/or maintenance.

C. Program Evaluation (20 Points)

Each proposed objective requires an evaluation component to assess its progress and ensure its completion. Also, include the evaluation activities in the work plan.

Describe the proposed plan to evaluate both outcomes and process. Outcome evaluation relates to the results identified in the objectives, and process evaluation relates to the work plan and activities of the project.

(1) For outcome evaluation, describe:

- What will the criteria be for determining success of each objective?
- What data will be collected to determine whether the objective was met?
- At what intervals will data be collected?
- Who will collect the data and their qualifications?
- How will the data be analyzed?
- How will the results be used?

(2) For process evaluation, describe:

- How will the projects be monitored and assessed for potential problems and needed quality improvements?
- Who will be responsible for monitoring and managing project improvements based on results of ongoing process improvements and what are their qualifications?
- How will ongoing monitoring be used to improve the projects?
- Describe any products, such as manuals or policies, that might be developed and how they might lend themselves to replication by others.
- How will the organization document what is learned throughout the projects' grant periods?

(3) Describe any evaluation efforts planned after the grant period has ended.

(4) Describe the ultimate benefit to the AI/AN population served by the applicant organization that will be derived from these projects.

D. Organizational Capabilities, Key Personnel and Qualifications (15 Points)

This section outlines the broader capacity of the organization to complete the project outlined in the work plan. It includes the identification of personnel responsible for completing tasks and the chain of responsibility for successful completion of the projects outlined in the work plans.

(1) Describe the organizational structure of the organization beyond health care activities, if applicable.

(2) Describe the ability of the organization to manage the proposed projects. Include information regarding similarly sized projects in scope and financial assistance, as well as other cooperative agreements/grants and projects successfully completed.

(3) Describe what equipment (*i.e.,* fax machine, phone, computer, etc.) and facility space (*i.e.,* office space) will be available for use during the proposed projects. Include information about any equipment not currently available that will be purchased through the cooperative agreement/grant.

(4) List key personnel who will work on the projects. Include title used in the work plans. In the Appendix, include position descriptions and resumes for all key personnel. Position descriptions should clearly describe each position and duties, indicating desired qualifications and experience requirements related to the proposed project. Resumes must indicate that the proposed staff member is qualified to carry out the proposed project activities. If a position is to be filled, indicate that information on the proposed position description.

(5) If personnel are to be only partially funded by this cooperative agreement, indicate the percentage of time to be allocated to this project and identify the resources used to fund the remainder of the individual's salary.

E. Categorical Budget and Budget Justification (10 Points)

This section should provide a clear estimate of the program costs and justification for expenses for the entire cooperative agreement period for each award. The budgets and budget justifications should be consistent with the tasks identified in the work plans. Because each of the two awards included in this announcement are funded through separate funding streams, the applicant must provide a separate budget and budget narrative for each of the two components and must account for costs separately.

(1) Provide a categorical budget for each of the 12-month budget periods requested for each of the two projects. One additional page per year addressing the developmental plans for each additional year of the project.

(2) If IDC are claimed, indicate and apply the current negotiated rate to the budget. Include a copy of the rate agreement in the Appendix. *See Section VI. Award Administration Information, 3. Indirect Costs.*

(3) Provide a narrative justification explaining why each line item is necessary or relevant to the proposed project. Include sufficient costs and other details to facilitate the determination that the cost is allowable (*i.e.,* equipment specifications, etc.).

Multi-Year Project Requirements

Projects requiring a second and/or third year must include a brief project narrative and budget (one additional page per year) addressing the developmental plans for each additional year of the project.

Additional documents can be uploaded as Appendix Items in Grants.gov

- Work plan, logic model and/or time line for proposed objectives.
- Position descriptions for key staff.
- Resumes of key staff that reflect current duties.
- Consultant or contractor proposed scope of work and letter of commitment (if applicable).
- Current Indirect Cost Agreement.
- Organizational chart.
- Map of area identifying project location(s).
- Additional documents to support narrative (*i.e.,* data tables, key news articles, etc.).

2. Review and Selection

Each application will be prescreened by the DGM staff for eligibility and completeness as outlined in the funding announcement. Applications that meet the eligibility criteria shall be reviewed for merit by the ORC based on evaluation criteria in this funding announcement. The ORC could be composed of both Tribal and Federal reviewers appointed by the Office of Direct Service and Contracting Tribes (ODSCT) to review and make recommendations on these applications. The technical review process ensures selection of quality projects in a national competition for limited funding. Incomplete applications and applications that are non-responsive to the eligibility criteria will not be referred to the ORC. The applicant will be notified via email of this decision by the Grants Management Officer of the DGM. Applicants will be notified by DGM, via email, to outline minor missing components (*i.e.,* budget narratives, audit documentation, key contact form) needed for an otherwise complete application. All missing documents must be sent to DGM on or before the due date listed in the email of notification of missing documents required.

To obtain a minimum score for funding by the ORC, applicants must address all program requirements and provide all required documentation.

VI. Award Administration Information

1. Award Notices

The Notice of Award (NoA) is a legally binding document signed by the Grants Management Officer and serves as the official notification of the grant award. The NoA will be initiated by the DGM in our grant system, GrantSolutions (*https://www.grantsolutions.gov*). Each entity that is approved for funding under this announcement will need to request or have a user account in GrantSolutions in order to retrieve their NoA. The NoA is the authorizing document for which funds are dispersed to the approved entities and reflects the amount of Federal funds awarded, the purpose of the grant, the terms and conditions of the award, the effective date of the award, and the budget/project period.

Disapproved Applicants

Applicants who received a score less than the recommended funding level for approval, 60 points, and were deemed to be disapproved by the ORC, will receive an Executive Summary Statement from the ODSCT within 30 days of the conclusion of the ORC outlining the strengths and weaknesses of their application submitted. The ODSCT will also provide additional contact information as needed to address questions and concerns as well as provide technical assistance if desired.

Approved But Unfunded Applicants

Approved but unfunded applicants that met the minimum scoring range and were deemed by the ORC to be "Approved", but were not funded due to lack of funding, will have their applications held by DGM for a period of one year. If additional funding becomes available during the course of FY 2016 the approved but unfunded application may be re-considered by the awarding program office for possible funding. The applicant will also receive an Executive Summary Statement from the IHS program office within 30 days of the conclusion of the ORC.

Note: Any correspondence other than the official NoA signed by an IHS Grants Management Official announcing to the Project Director that an award has been made to their organization is not an authorization to implement their program on behalf of IHS.

2. Administrative Requirements

Cooperative agreements are administered in accordance with the following regulations, policies, and OMB cost principles:

A. The criteria as outlined in this Program Announcement.

B. Administrative Regulations for Grants:

- Uniform Administrative Requirements for HHS Awards, located at 45 CFR part 75.

C. Grants Policy:

- HHS Grants Policy Statement, Revised 01/07.

D. Cost Principles:

- Uniform Administrative Requirements for HHS Awards, "Cost Principles," located at 45 CFR part 75, subpart E.

E. Audit Requirements:

- Uniform Administrative Requirements for HHS Awards, "Audit Requirements," located at 45 CFR part 75, subpart F.

3. Indirect Costs

This section applies to all grant recipients that request reimbursement of IDC in their grant application. In accordance with HHS Grants Policy Statement, Part II–27, IHS requires applicants to obtain a current IDC rate agreement prior to award. The rate agreement must be prepared in accordance with the applicable cost principles and guidance as provided by the cognizant agency or office. A current rate covers the applicable grant activities under the current award's budget period. If the current rate is not on file with the DGM at the time of award, the IDC portion of the budget will be restricted. The restrictions remain in place until the current rate is provided to the DGM.

Generally, IDC rates for IHS grantees are negotiated with the Division of Cost Allocation (DCA) *https://rates.psc.gov/* and the Department of Interior (Interior Business Center) *https://www.doi.gov/ibc/services/finance/indirect-Cost-Services/indian-tribes.* For questions regarding the indirect cost policy, please call the Grants Management Specialist listed under "Agency Contacts" or the main DGM office at (301) 443–5204.

4. Reporting Requirements

The grantee must submit required reports consistent with the applicable deadlines. Failure to submit required reports within the time allowed may result in suspension or termination of an active grant, withholding of additional awards for the project, or other enforcement actions such as withholding of payments or converting to the reimbursement method of payment. Continued failure to submit required reports may result in one or both of the following: (1) The imposition of special award provisions; and (2) the non-funding or non-award of other eligible projects or activities. This requirement applies whether the delinquency is attributable to the failure of the grantee organization or the individual responsible for preparation of the reports. Per DGM policy, all reports are required to be submitted electronically by attaching them as a "Grant Note" in GrantSolutions. Personnel responsible for submitting reports will be required to obtain a login and password for GrantSolutions. Please see the Agency Contacts list in section VII for the systems contact information.

The reporting requirements for this program are noted below.

A. Progress Reports

Program progress reports are required semi-annually within 30 days after the budget period ends. These reports must include a brief comparison of actual accomplishments to the goals established for the period, or, if applicable, provide sound justification for the lack of progress, and other pertinent information as required. A final report must be submitted within 90 days of expiration of the budget/project period.

B. Financial Reports

Federal Financial Report FFR (SF–425), Cash Transaction Reports are due 30 days after the close of every calendar quarter to the Payment Management Services, HHS at: *http://www.dpm.psc.gov.* It is recommended that the applicant also send a copy of the FFR (SF–425) report to the Grants Management Specialist. Failure to submit timely reports may cause a disruption in timely payments to the organization.

Grantees are responsible and accountable for accurate information being reported on all required reports: The Progress Reports and Federal Financial Report.

C. Federal Sub-Award Reporting System (FSRS)

This award may be subject to the Transparency Act sub-award and executive compensation reporting requirements of 2 CFR part 170.

The Transparency Act requires the OMB to establish a single searchable database, accessible to the public, with information on financial assistance awards made by Federal agencies. The Transparency Act also includes a requirement for recipients of Federal grants to report information about first-tier sub-awards and executive compensation under Federal assistance awards.

IHS has implemented a Term of Award into all IHS Standard Terms and Conditions, NoAs and funding announcements regarding the FSRS reporting requirement. This IHS Term of Award is applicable to all IHS grant and cooperative agreements issued on or after October 1, 2010, with a $25,000 sub-award obligation dollar threshold met for any specific reporting period. Additionally, all new (discretionary) IHS awards (where the project period is made up of more than one budget period) and where: (1) The project period start date was October 1, 2010 or after and (2) the primary awardee will have a $25,000 sub-award obligation dollar threshold during any specific reporting period will be required to address the FSRS reporting. For the full IHS award term implementing this requirement and additional award applicability information, visit the DGM Grants Policy Web site at: http://www.ihs.gov/dgm/policytopics/.

D. Compliance With Executive Order 13166 Implementation of Services Accessibility Provisions for All Grant Application Packages and Funding Opportunity Announcements

Recipients of federal financial assistance (FFA) from HHS must administer their programs in compliance with federal civil rights law. This means that recipients of HHS funds must ensure equal access to their programs without regard to a person's race, color, national origin, disability, age and, in some circumstances, sex and religion. This includes ensuring your programs are accessible to persons with limited English proficiency. HHS provides guidance to recipients of FFA on meeting their legal obligation to take reasonable steps to provide meaningful access to their programs by persons with limited English proficiency. Please see *http://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/guidance-federal-financial-assistance-recipients-title-VI/.*

The HHS Office for Civil Rights (OCR) also provides guidance on complying with civil rights laws enforced by HHS. Please see *http://www.hhs.gov/civil-rights/for-individuals/section-1557/index.html;* and *http://www.hhs.gov/*

civil-rights/index.html. Recipients of FFA also have specific legal obligations for serving qualified individuals with disabilities. Please see *http://www.hhs.gov/civil-rights/for-individuals/disability/index.html.* Please contact the HHS OCR for more information about obligations and prohibitions under federal civil rights laws at *http://www.hhs.gov/civil-rights/for-individuals/disability/index.html* or call 1–800–368–1019 or TDD 1–800–537–7697. Also note it is an HHS Departmental goal to ensure access to quality, culturally competent care, including long-term services and supports, for vulnerable populations. For further guidance on providing culturally and linguistically appropriate services, recipients should review the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care at *http://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53.*

Pursuant to 45 CFR 80.3(d), an individual shall not be deemed subjected to discrimination by reason of his/her exclusion from benefits limited by federal law to individuals eligible for benefits and services from the IHS.

Recipients will be required to sign the HHS–690 Assurance of Compliance form which can be obtained from the following Web site: *http://www.hhs.gov/sites/default/files/forms/hhs-690.pdf,* and send it directly to the: U.S. Department of Health and Human Services, Office of Civil Rights, 200 Independence Ave. SW., Washington, DC 20201.

E. Federal Awardee Performance and Integrity Information System (FAPIIS)

The IHS is required to review and consider any information about the applicant that is in the Federal Awardee Performance and Integrity Information System (FAPIIS) before making any award in excess of the simplified acquisition threshold (currently $150,000) over the period of performance. An applicant may review and comment on any information about itself that a federal awarding agency previously entered. IHS will consider any comments by the applicant, in addition to other information in FAPIIS in making a judgment about the applicant's integrity, business ethics, and record of performance under federal awards when completing the review of risk posed by applicants as described in 45 CFR 75.205.

As required by 45 CFR part 75 Appendix XII of the Uniform Guidance, non-federal entities (NFEs) are required to disclose in FAPIIS any information about criminal, civil, and administrative proceedings, and/or affirm that there is no new information to provide. This applies to NFEs that receive federal awards (currently active grants, cooperative agreements, and procurement contracts) greater than $10,000,000 for any period of time during the period of performance of an award/project.

Mandatory Disclosure Requirements

As required by 2 CFR part 200 of the Uniform Guidance, and the HHS implementing regulations at 45 CFR part 75, effective January 1, 2016, the Indian Health Service must require a non-federal entity or an applicant for a federal award to disclose, in a timely manner, in writing to the IHS or pass-through entity all violations of federal criminal law involving fraud, bribery, or gratutity violations potentially affecting the federal award.

Submission is required for all applicants and recipients, in writing, to the IHS and to the HHS Office of Inspector General all information related to violations of Federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the Federal award. 45 CFR 75.113

Disclosures must be sent in writing to: U.S. Department of Health and Human Services, Indian Health Service, Division of Grants Management, ATTN: Robert Tarwater, Director, 5600 Fishers Lane, Mailstop: 09E70, Rockville, Maryland 20857. (Include "Mandatory Grant Disclosures" in subject line.) *Ofc:* (301) 443–5204. *Fax:* (301) 594–0899. *email: Robert.Tarwater@ihs.gov. AND* U.S. Department of Health and Human Services, Office of Inspector General, ATTN: Mandatory Grant Disclosures, Intake Coordinator, 330 Independence Avenue SW., Cohen Building, Room 5527, Washington, DC 20201. *URL: http://oig.hhs.gov/fraud/reportfraud/index.asp* (Include "Mandatory Grant Disclosures" in subject line) *Fax:* (202) 205–0604 (Include "Mandatory Grant Disclosures" in subject line.) or *email: MandatoryGranteeDisclosures@oig.hhs.gov.*

Failure to make required disclosures can result in any of the remedies described in 45 CFR 75.371 Remedies for noncompliance, including suspension or debarment (See 2 CFR parts 180 and 376 and 31 U.S.C. 3321).

VII. Agency Contacts

1. Questions on the programmatic issues may be directed to: Ms. Michelle EagleHawk, Deputy Director, ODSCT, 5600 Fishers Lane, Mail Stop: 8E17, Rockville, Maryland 20857, *Telephone:* (301) 443–1104, *email: Michelle.EagleHawk@ihs.gov.*

2. Questions on grants management and fiscal matters may be directed to: Ms. Patience Musikikongo, DGM, Grants Management Specialist, 5600 Fishers Lane, Mail Stop: 09E70, Rockville, MD 20857, *Telephone:* (301) 443–2059, *Fax:* (301) 594–0899, *email: Patience.Musikikongo@ihs.*

3. Questions on systems matters may be directed to: Paul Gettys, Grant Systems Coordinator, 5600 Fishers Lane, Mail Stop: 09E70, Rockville, MD 20857, *Phone:* (301) 443–2114; or the DGM main line 301–443–5204, *Fax:* (301) 594–0899, *email: Paul.Gettys@ihs.gov.*

VIII. Other Information

The Public Health Service strongly encourages all cooperative agreement and contract recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. In addition, Public Law 103–227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of the facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the HHS mission to protect and advance the physical and mental health of the American people.

Dated: July 7, 2016.

Elizabeth A. Fowler,

Deputy Director for Management Operations, Indian Health Service.

[FR Doc. 2016–16819 Filed 7–14–16; 8:45 am]

BILLING CODE 4165–16–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Alcohol Abuse and Alcoholism, Special Emphasis Panel; AA–1 and AA–4 Study Section, Conflict Grant Applications.

Date: July 27, 2016.

Time: 1:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute on Alcohol Abuse and Alcoholism, 5635 Fishers Lane, Rockville, MD 20892 (Telephone Conference Call).

Contact Person: Philippe Marmillot, Ph.D., National Institutes of Health, National Institute on Alcohol Abuse and Alcoholism, 5635 Fishers Lane, Rm. 2017, Bethesda, MD 20892, 301–443–2861, *marmillotp@mail.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.271, Alcohol Research Career Development Awards for Scientists and Clinicians; 93.272, Alcohol National Research Service Awards for Research Training; 93.273, Alcohol Research Programs; 93.891, Alcohol Research Center Grants; 93.701, ARRA Related Biomedical Research and Research Support Awards, National Institutes of Health, HHS)

Dated: July 11, 2016.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–16706 Filed 7–14–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; the Study of the Global Cancer Project Map (NCI)

Summary: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Cancer Institute, the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) The quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

To Submit Comments and for Further Information: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Kalina Duncan, Program Director, Center for Global Health, 9609 Medical Center Drive, 3W258, Rockville, MD 20850 or call non-toll-free number (240) 276–5804 or Email your request, including your address to: *kalina.duncan@nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

Comment Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Proposed Collection: The Study of the Global Cancer Project Map, 0925–NEW, National Cancer Institute (NCI), National Institutes of Health (NIH).

Need and Use of Information Collection: This is a new information collection request for the Study of the Global Cancer Project Map (GCPM) for three years. Information will be collected from health care professionals and researchers in an effort to catalog international efforts related to cancer research, care, and outreach by integrating cancer control program and research project information from various organizations worldwide.

The Global Cancer Project Map (GCPM) is a new, interactive, web-based tool that enables healthcare professionals and researchers to make informed decisions, initiate partnerships, and develop ideas for collaborations in cancer control. Its features allow people to (1) search for collaborators and projects by cancer type, project type, and country; (2) visualize information pertinent to each project on an interactive world map; (3) initiate contact with principal investigators and program directors; and (4) overlay heat maps of epidemiological measures that provide a representation of the burden of cancer by country.

The primary goals of GCPM are to facilitate the building of collaborations across organizations; accelerate progress, ensure a balanced investment of resources, and align global cancer care and control efforts; and continue data collection from national and international organizations to develop the Map as a resource to view and better understand international efforts in cancer research and control.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 167.

ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Type of respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual burden hours
Global Cancer Project Map submission form (Attach 3).	Chief Executives, Medical Scientists, Health Educators, Family/General Practitioners, Registered Nurses, Medical and Health Services Managers.	1,000	1	10/60	167
Totals		1,000	1,000		167

Dated: July 8, 2016.

Karla Bailey,

Project Clearance Liaison, National Cancer Institute, NIH.

[FR Doc. 2016–16707 Filed 7–14–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5907–N–29]

Federal Property Suitable as Facilities To Assist the Homeless

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: This Notice identifies unutilized, underutilized, excess, and surplus Federal property reviewed by HUD for suitability for use to assist the homeless.

FOR FURTHER INFORMATION CONTACT: Juanita Perry, Department of Housing and Urban Development, 451 Seventh Street SW., Room 7266, Washington, DC 20410; telephone (202) 402–3970; TTY number for the hearing- and speech-impaired (202) 708–2565 (these telephone numbers are not toll-free), call the toll-free Title V information line at 800–927–7588 or send an email to *title5@hud.gov.*

SUPPLEMENTARY INFORMATION: In accordance with 24 CFR part 581 and section 501 of the Stewart B. McKinney Homeless Assistance Act (42 U.S.C. 11411), as amended, HUD is publishing this Notice to identify Federal buildings and other real property that HUD has reviewed for suitability for use to assist the homeless. The properties were reviewed using information provided to HUD by Federal landholding agencies regarding unutilized and underutilized buildings and real property controlled by such agencies or by GSA regarding its inventory of excess or surplus Federal property. This Notice is also published in order to comply with the December 12, 1988 Court Order in *National Coalition for the Homeless* v. *Veterans Administration,* No. 88–2503–OG (D.D.C.).

Properties reviewed are listed in this Notice according to the following categories: Suitable/available, suitable/unavailable, and suitable/to be excess, and unsuitable. The properties listed in the three suitable categories have been reviewed by the landholding agencies, and each agency has transmitted to HUD: (1) Its intention to make the property available for use to assist the homeless, (2) its intention to declare the property excess to the agency's needs, or (3) a statement of the reasons that the property cannot be declared excess or made available for use as facilities to assist the homeless.

Properties listed as suitable/available will be available exclusively for homeless use for a period of 60 days from the date of this Notice. Where property is described as for ''off-site use only'' recipients of the property will be required to relocate the building to their own site at their own expense. Homeless assistance providers interested in any such property should send a written expression of interest to HHS, addressed to: Ms. Theresa M. Ritta, Chief Real Property Branch, the Department of Health and Human Services, Room 12–07, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857, (301) 443–2265 (This is not a toll-free number.) HHS will mail to the interested provider an application packet, which will include instructions for completing the application. In order to maximize the opportunity to utilize a suitable property, providers should submit their written expressions of interest as soon as possible. For complete details concerning the processing of applications, the reader is encouraged to refer to the interim rule governing this program, 24 CFR part 581.

For properties listed as suitable/to be excess, that property may, if subsequently accepted as excess by GSA, be made available for use by the homeless in accordance with applicable law, subject to screening for other Federal use. At the appropriate time, HUD will publish the property in a Notice showing it as either suitable/available or suitable/unavailable.

For properties listed as suitable/unavailable, the landholding agency has decided that the property cannot be declared excess or made available for use to assist the homeless, and the property will not be available.

Properties listed as unsuitable will not be made available for any other purpose for 20 days from the date of this Notice. Homeless assistance providers interested in a review by HUD of the determination of unsuitability should call the toll free information line at 1–800–927–7588 or send an email to *title5@hud.gov* for detailed instructions, or write a letter to Ann Marie Oliva at the address listed at the beginning of this Notice. Included in the request for review should be the property address (including zip code), the date of publication in the **Federal Register**, the landholding agency, and the property number.

For more information regarding particular properties identified in this Notice (*e.g.,* acreage, floor plan, condition of property, existing sanitary facilities, exact street address), providers should contact the appropriate landholding agencies at the following addresses: AGRICULTURE: Ms. Debra Kerr, Department of Agriculture, OPPM, Property Management Division, Agriculture South Building, 300 7th Street SW., Washington, DC 20024, (202) 720–8873; AIR FORCE: Mr. Robert E. Moriarty, P.E., AFCEC/CI, 2261 Hughes Avenue, Ste. 155, JBSA Lackland, TX 78236–9853, (315) 225–7384; COE: Ms. Brenda Johnson-Turner, HQUSACE/CEMP–CR, 441 G Street NW., Washington, DC 20314, (202) 761–7238; ENERGY: Mr. David Steinau, Department of Energy, Office of Asset Management (MA–50), 1000 Independence Ave. SW., Washington, DC 20585, (202) 287–1503; GSA: Mr. Flavio Peres, General Services Administration, Office of Real Property Utilization and Disposal, 1800 F Street NW., Room 7040, Washington, DC 20405, (202) 501–0084; INTERIOR: Mr. Michael Wright, Acquisition & Property Management, Department of the Interior, 3960 N. 56th Ave. #104, Hollywood, FL 33021; (443) 223–4639; NASA: Mr. William Brodt, National Aeronautics and Space Administration, 300 E Street SW., Room 2P85, Washington, DC 20546, (202) 358–1117; NAVY: Mr. Steve Matteo, Department of the Navy, Asset Management Division, Naval Facilities Engineering Command, Washington Navy Yard, 1330 Patterson Ave. SW., Suite 1000, Washington, DC 20374; (202) 685–9426; (These are not toll-free numbers).

Dated: July 7, 2016.

Brian P. Fitzmaurice,

Director, Division of Community Assistance, Office of Special Needs Assistance Programs.

TITLE V, FEDERAL SURPLUS PROPERTY PROGRAM FEDERAL REGISTER REPORT FOR 07/15/2016

Suitable/Available Properties

Building

Alaska

Mobile Home #1; 1072
Forest Service Compound
Yakutat AK 99689
Landholding Agency: Agriculture
Property Number: 15201620050
Status: Excess
Comments: off-site removal only; 30+ yrs. old; 1,087 sq. ft.; residential; 24+ mos. vacant; poor condition; $6,500 (estimate) in repairs; contact Agriculture for more information.

Mobile Home
Forest Service Compound
Thorne Bay AK 99919

Landholding Agency: Agriculture
Property Number: 15201630001
Status: Excess
Directions: #1–8403
Comments: off-site removal only; 27+ yrs. old; 967 sq. ft.; residential; poor condition; vacant 12+ mos.; $6,500 estimate for maintenance; contact Agriculture for more information.

Mobile Home #3; 1074
Forest Service Compound
Yakutat AK 99689
Landholding Agency: Agriculture
Property Number: 15201630002
Status: Excess
Comments: off-site removal only; 25+ yrs. old; 1,140 sq. ft.; residential; 24+ mos. vacant; poor condition; $6,500 estimate repairs; contact Agriculture for more information.

Port Houghton Cabin
15201630003 of Juneau Ak.
45 miles North of Petersburg AK.
Petersburg AK
Landholding Agency: Agriculture
Property Number: 15201630003
Status: Excess
Directions: #1060
Comments: off-site removal only; 19+ yrs. old; 660 sq. ft.; cabin; 12+ mos. vacant; good condition; $2,000 maintenance; contact Agriculture for more information.

Oregon

China Hat Food Cellar
(1259.004621)
NF Road 18, East Bend Fort Rock
La Pine OR 97739
Landholding Agency: Agriculture
Property Number: 15201620049
Status: Excess
Directions: Building #2608, Region 06, Forest 01; cinder block structure w/no utilities; major repairs/rehab prior to use
Comments: off-site removal only; 56+ yrs. old; 120 sq. ft.; storage; vacant 180+ mos.; very poor condition; contact Agriculture for more information.

Wisconsin

William J. Huempfner USARC
2426 Prairie Avenue
Beloit WI 54656
Landholding Agency: GSA
Property Number: 54201620028
Status: Surplus
GSA Number: I–D–WI–612
Directions: Landholding Agency: Army; Disposal Agency: GSA
Comments: 54+ yrs. old; 4,316 sq. ft.; office; can only access through neighboring company parking lot; sits on 3.56 acres of land; contact GSA for more information.

Bursch Residence, Garage and
and Pole Shed Trace 12–14
Bursch Residence, Garage and Pole Shed
Somerset WI 54025
Landholding Agency: Interior
Property Number: 61201620019
Status: Excess
Directions: Trace 12–14
Comments: off-site removal only; 60+ yrs. old; 1,832 sq. ft.; difficult to remove due to size/type; residential; 19+ mos. vacant; fair condition; escort required; contact Interior for more information.

Land

Tennessee

Parcel G, 20.96+ acres
Bethel Valley Road
Oak Ridge TN 37830
Landholding Agency: GSA
Property Number: 54201630001
Status: Surplus
GSA Number: 4–B–TN–0664–AE
Directions: Landholding Agency: The parcel is located off Bethel Valley Road southeast of the intersection of Bethel Valley and Scarboro Roads. Landholding Agency: DOE; Disposal Agency: GSA; vacant land w/mixed grasses, herbaceous plants, large shrubs, & scattered trees; groundwater not permitted for use for agricultural, drinking, or industrial purposes; must connect to a regulatory approved water system to use property; creek flows through site with floodplain & wetlands; sanitary water sewer easements on property; DOE will retain an ingress/egress easement on the property; man-made ponds formerly used to treat swine waste.
Comments: contact GSA for more details regarding property

Unsuitable Properties

Building

California

YSC Tire Building, 1030 So. Main Street, Yreka CA 96097, Landholding Agency: Agriculture.
Property Number: 15201620051
Status: Excess
Directions: Klamath National Forest Center, Yreka Service Center; RP#4901009 CN#1014.003771 UAI#N/A
Comments: property located within floodway which has not been corrected or contained.
Reasons: Floodway.

High Glade Lookout, Storage Shed, 39.209572 N., 122.810803 W, Elevation 4,847, Nice CA 95464.
Landholding Agency: Agriculture
Property Number: 15201630004
Status: Unutilized
Directions: RP #12126 CN #2117.003931
Comments: documented deficiencies: concrete roof collapsing; exterior walls cracking; clear threat to physical safety
Reasons: Extensive deterioration

Florida

3 Buildings, Cape Canaveral Air Force Station, CCAFS FL.
Landholding Agency: NASA
Property Number: 71201630001
Status: Unutilized
Directions: 77630; 80700J; 80700K
Comments: public access denied and no alternative method to gain access without compromising national security.
Reasons: Secured Area

13 Buildings
Kennedy Space Center
KSC FL 32899
Landholding Agency: NASA
Property Number: 71201630002
Status: Unutilized
Directions: J8–1703; K6–0792A; K6–1446E; K6–1446L; K6–1996L; K6–1996U; K6–1996Q; K6–1996V; L7–0988; K7–0852; M6–0486N; TRM–051; J7–0331
Comments: public access denied and no alternative method to gain access without compromising national security.
Reasons: Secured Area

60541
Cape Canaveral Air Force Station
CCAFS FL 32929
Landholding Agency: NASA
Property Number: 71201630003
Status: Unutilized
Comments: public access denied and no alternative method to gain access without compromising national security.
Reasons: Secured Area

20 Buildings
Kennedy Space Center
KSC FL 32899
Landholding Agency: NASA
Property Number: 71201630004
Status: Unutilized
Directions: M7–0433; M7–0656; J6–0306; K6–1298; K6–1844E; M6–0537; M6–0584; J7–0331; J6–0407; J8–1614A; J8–1614; K6–1446D; J8–2059; K6–1844E; K6–1844D; M6–0392; K6–2196; M6–0946; K6–1446; TRI–0477
Comments: public access denied and no alternative method to gain access without compromising national security.
Reasons: Secured Area

Georgia

Savannah HHIAP
Facility 1906
XDQU
1401 Robert B. Miller Dr.
Garden City GA 31408
Landholding Agency: Air Force
Property Number: 18201630002
Status: Excess
Comments: public access denied and no alternative method to gain access without compromising national security.
Reasons: Secured Area

Maryland

Feidt House Tract 79–114
Across from 10692 Dam 5 Road
Clear Spring MD 21722
Landholding Agency: Interior
Property Number: 61201620018
Status: Unutilized
Comments: documented deficiencies: documentation provided represents a clear threat to personal physical safety; largely collapsed & is a complete loss; no remaining structural integrity.
Reasons: Extensive deterioration

Anthony/Donegan House
Tract 92–104
1609 Pearre Road
Hancock MD 21750
Landholding Agency: Interior
Property Number: 61201620021
Status: Unutilized
Comments: property loc. w/in floodway which has not been correct or contained; Doc. deficiencies: doc. provided represents a clear threat to personal physical safety; largely collapsed & no remaining structure.
Reasons: Extensive deterioration; Floodway

Clay House Tract 92–103
150 Feet West of 1609 Pearre Road
Hancock MD 21750
Landholding Agency: Interior
Property Number: 61201620022

Status: Unutilized
Comments: property loc. w/in floodway which has not been correct or contained; Doc. deficiencies: doc. provided represents a clear threat to personal physical safety; largely collapsed & no remaining structure.
Reasons: Floodway; Extensive deterioration

Ferry Hill Cottage
Tract 31–108
16500 Shepherdstown Pike
Sharpsburg MD 21782
Landholding Agency: Interior
Property Number: 61201630001
Status: Unutilized
Comments: documented deficiencies: integrity of structure is very poor; extensive water and mold damage; clear threat to physical safety.
Reasons: Extensive deterioration

Missouri

2 each Vault Toilets
Route 2 Box 2160 Pomme de Terre Lake Project
Damsite Park, Hickory County
Hermitage MO 65668
Landholding Agency: COE
Property Number: 31201620005
Status: Underutilized
Comments: property located within floodway which has not been correct or contained.
Reasons: Floodway

New Mexico

Los Alamos National Laboratory
18–0311
Los Alamos NM 87545
Landholding Agency: Energy
Property Number: 41201630001
Status: Excess
Directions: #18–0311
Comments: public access denied and no alternative method to gain access without compromising national security.
Reasons: Secured Area

Oregon

China Hat Bunkhouse
(1256.004621)
NF Road 18, East Bend Fort Rock
La Pine OR 97739
Landholding Agency: Agriculture
Property Number: 15201620047
Status: Excess
Directions: Building #1313, Region 06, Forest 01
Comments: documented deficiencies: extensive rodent infestation; ceiling damage; holes in walls; clear threat to physical safety.
Reasons: Extensive deterioration

China Hat Guard House
(1255.004621)
NF Road 18, East Bend Fort Rock
La Pine OR 97739
Landholding Agency: Agriculture
Property Number: 15201620048
Status: Excess
Directions: Building #1312, Region 06, Forest 01
Comments: documented deficiencies: Extensive rodent infestation; ceiling damage; holes in walls; clear threat to physical safety.
Reasons: Extensive deterioration.

Puerto Rico

Building 10
Punta Salinas Radar Site
Toa Baja PR
Landholding Agency: Air Force
Property Number: 18201630001
Status: Unutilized
Comments: Public access denied and no alternative to gain access without compromising national security.
Reasons: Secured Area

Texas

Building 4143
Fort Worth Joint Reserve Base
Fort Worth TX 76127
Landholding Agency: Navy
Property Number: 77201630001
Status: Unutilized
Comments: Public access denied and no alternative method to gain access without compromising national security.
Reasons: Secured Area

Wisconsin

Little Sand Bay Visitor Center
32660 Little Sand Bay Road
Bayfield WI 54814
Landholding Agency: Interior
Property Number: 61201620020
Status: Excess
Comments: Documented deficiencies: Documentation provided represents a clear threat to personal physical safety; falling & deteriorating foundation; potential hanta virus; mold & asbestos; contaminated soil.
Reasons: Extensive deterioration

[FR Doc. 2016–16462 Filed 7–14–16; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLWY910000 L16100000 XX0000]

Notice of Public Meeting; Wyoming Resource Advisory Council

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of public meeting.

SUMMARY: In accordance with the Federal Land Policy and Management Act of 1976 and the Federal Advisory Committee Act of 1972, the U.S. Department of the Interior, Bureau of Land Management (BLM) Wyoming Resource Advisory Council (RAC) will meet as indicated below.

DATES: The meeting is scheduled for, Tuesday, August 9, 2016, from 1 p.m. to 5 p.m.; Wednesday, August 10, 2016, from 8 a.m. to 5 p.m.; and Thursday, August 11, 2016, from 8 a.m. to noon.

ADDRESSES: The meeting will be conducted at the BLM Worland Field Office, 101 South 23rd, Worland, Wyoming.

FOR FURTHER INFORMATION CONTACT: Kristen Lenhardt, Chief of Communications, Wyoming State Office, 5353 Yellowstone Road, Cheyenne, WY 82009; telephone: 307–775–6015; email: *klenhard@blm.gov*.

Persons who use a telecommunications device for the deaf may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FIRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: This 10-member RAC advises the Secretary of the Interior on a variety of management issues associated with public land management in Wyoming. Planned agenda topics for the August meeting (see **DATES**) include discussions on invasive species and follow-up to previous RAC meetings. On Thursday, August 11, the meeting will begin with a public comment period at 8 a.m. Depending on the number of persons wishing to comment and time available, the time for individual oral comments may be limited. If there are no members of the public interested in speaking, the meeting will move promptly to the next agenda item. The public may also submit written comments to the RAC by emailing *klenhard@blm.gov,* with the subject line "RAC Public Comment" or by submitting comments during the meeting to the Chief of Communications. Typed or written comments will be provided to RAC members as part of the meeting's minutes.

Dated: July 11, 2016.

Mary Jo Rugwell,

State Director.

[FR Doc. 2016–16746 Filed 7–14–16; 8:45 am]

BILLING CODE 4310–22–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLMT922200–16–L13100000–FI0000–P; NDM 98943]

Notice of Proposed Reinstatement of Terminated Oil and Gas Lease NDM 98943, North Dakota

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: Linn Energy Holdings LLC, MBI Oil and Gas LLC, Montana Oil Properties Inc., Slawson Exploration Company Inc. and Stewart Geological Inc. have timely filed a petition for reinstatement of competitive oil and gas lease NDM 98943, which is located in Mountrail County, North Dakota. The petition was filed on time and consistent with the Mineral Leasing Act of 1920. The lessee has paid the required rentals accruing from the date of termination. No leases were issued that affect these lands.

FOR FURTHER INFORMATION CONTACT: Kimberly Werven, Chief, Fluids Adjudication Section, Bureau of Land Management Montana State Office, 5001 Southgate Drive, Billings, Montana 59101–4669, 406–896–5091, *kwerven@blm.gov.* Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FIRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: In connection with this lease reinstatement, the lessees agree to new lease terms for rentals and royalties specified in the applicable regulations—$10 per acre, or fraction thereof, per year, and 16-⅔ percent, respectively. The lessees agree to additional or amended stipulations. The lessees paid the $500 administration fee for the reinstatement of the lease and $163 cost for publishing this Notice. The lessees also agreed to the amended lease stipulations described in the associated Reinstatement Certification. As result, the lessees have met the requirements for reinstatement of the lease under Sec. 31(d) and (e) of the Mineral Leasing Act of 1920. We are proposing to reinstate the lease, effective the date of termination subject to the:

- Original terms and conditions of the lease;
- Additional and amended stipulations as specified in the Reinstatement Certification;
- Increased rental of $10 per acre;
- Increased royalty of 16-⅔ percent; and
- $163 cost of publishing this Notice.

Kimberly Werven,

Chief, Fluids Adjudication Section.

[FR Doc. 2016–16777 Filed 7–14–16; 8:45 am]

BILLING CODE 4310–DN–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–PWR–PWRO–21126; PX.PR113509M.00.1]

Record of Decision for the Hawaii Volcanoes National Park General Management Plan/Wilderness Study; Final Environmental Impact Statement, Hawaii County, Hawaii

AGENCY: National Park Service, Interior.

ACTION: Notice of Availability.

SUMMARY: The National Park Service (NPS) has prepared and approved a Record of Decision for the General Management Plan/Wilderness Study/Final Environmental Impact Statement (GMP/WS/EIS) for Hawaii Volcanoes National Park. Approval of the GMP/WS/EIS culminates an extensive public engagement and environmental impact analysis effort that began in 2009.

ADDRESSES: Those wishing to review the Record of Decision may obtain a copy by submitting their request to the Superintendent, Hawaii Volcanoes National Park, P.O. Box 52, Hawaii National Park, HI 96718–0052.

FOR FURTHER INFORMATION CONTACT: Cindy Orlando, Superintendent, telephone (808) 985–6026 or email *NPS_HAVO_Planning@nps.gov.*

SUPPLEMENTARY INFORMATION: This process was conducted pursuant to the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*) and the implementing regulations promulgated by the Council on Environmental Quality (40 CFR part 1505.2). The original Notice of Intent (NOI) initiating the conservation planning and environmental impact analysis process appeared in the **Federal Register** on April 13, 2009. A revised NOI expanding the scope of the GMP to include a wilderness study was published December 2, 2011. Based on information obtained from extensive public outreach, three alternatives were developed. The NPS consulted with park partners; Native Hawaiians; the State Historic Preservation Officer; and other federal and state agencies. The Draft EIS was released on May 1, 2015, for a 60-day review and comment period. In addition to the numerous public meetings held during public scoping and alternatives development, the NPS held one public meeting at the park's visitor center on June 10, 2015, to share information and gather feedback on the Draft EIS. This meeting also included a public hearing on the wilderness study. Overall, 32 pieces of correspondence were received during the public review period. No new substantive comments were received. With due consideration for the minimal public and agency response, the NPS utilized an abbreviated format in preparing the Final EIS. The legally required 30-day "wait period" was initiated on March 11, 2016, with the Environmental Protection Agency's **Federal Register** publication of the notice of filing and release of the GMP/Final EIS. The NPS evaluated the environmental consequences of two action alternatives and a no-action alternative. These alternatives described varying means to provide appropriate types and levels of access for visitors and authorized users, preserve wilderness character, protect cultural and natural resources, and adhere to legally required management and preservation objectives.

Alternative 2 (agency-preferred) has been selected for implementation. This is also the environmentally-preferred course of action, which emphasizes resource stewardship and preservation while strengthening and broadening opportunities to connect people with the volcanic world treasure, Hawaii Volcanoes National Park, and providing a wide range of high quality visitor experiences based on different geographic areas within the park. The GMP also proposes to seek legislation to include Olaa (9,679 acres) within the formal park boundary and to acquire several parcels totaling 21,381 acres, including the Great Crack and Pohue Bay. The Wilderness Study proposes wilderness designation of the lands found eligible in Kahuku (121,015 acres) as a natural extension of the existing wilderness within the park.

For a park that protects two of the most continuously active shield volcanoes in the world, the new Hawaii Volcanoes National Park GMP defines a clear direction for resource preservation and visitor experience over the next 20 years. The GMP provides a framework for proactive decision making, which will allow park managers to effectively address future opportunities and problems. The approved GMP will also serve as the basis for future detailed management documents, such as wilderness stewardship plans, trails management plans, and project implementation plans.

Dated: May 24, 2016.

Patricia L. Neubacher,

Acting Regional Director, Pacific West Region.

[FR Doc. 2016–16744 Filed 7–14–16; 8:45 am]

BILLING CODE 4312–FF–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NRNHL–21417; PPWOCRADI0, PCU00RP14.R50000]

National Register of Historic Places; Notification of Pending Nominations and Related Actions

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The National Park Service is soliciting comments on the significance of properties nominated before June 25, 2016, for listing or related actions in the National Register of Historic Places.

DATES: Comments should be submitted by August 1, 2016.

ADDRESSES: Comments may be sent via U.S. Postal Service to the National Register of Historic Places, National Park Service, 1849 C St. NW., MS 2280, Washington, DC 20240; by all other carriers, National Register of Historic Places, National Park Service, 1201 Eye St. NW., 8th Floor, Washington, DC 20005; or by fax, 202–371–6447.

SUPPLEMENTARY INFORMATION: The properties listed in this notice are being considered for listing or related actions in the National Register of Historic Places. Nominations for their consideration were received by the National Park Service before June 25, 2016. Pursuant to section 60.13 of 36 CFR part 60, written comments are being accepted concerning the significance of the nominated properties under the National Register criteria for evaluation.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

ALABAMA

Jefferson County

Downtown Birmingham Historic District (Boundary Increase III), Roughly bounded by 1st & 4th Aves., N., 20th St., N. & US 31, Birmingham, 16000489

ARIZONA

Maricopa County

Welnick Arcade Market and Liefgreen Seed Company Building, 341–345 W. Van Buren St., Phoenix, 16000490

COLORADO

Grand County

Smith—Eslick Cottage Court, 729 Lake Ave., Grand Lake, 16000491

ILLINOIS

Cook County

United States Customs House, 610 Canal St., Chicago, 16000492

KENTUCKY

Campbell County

Hubbard, Harlan, Studio, 129 Highland Ave., Fort Thomas, 16000493

Fayette County

Edgewood, 5910 Winchester Rd., Lexington, 16000494

Henry County

New Castle Historic Commercial District, Main & Main Cross Sts., New Castle, 16000495

Hopkins County

Madisonville Tuberculosis Hospital (Kentucky State Tuberculosis Hospitals, 1946–1950 MPS), 625 Hospital Dr., Madisonville, 16000496

Jefferson County

Afton, Wood F., Hall, Simmons University, 1811 Dumesnil St., Louisville, 16000497
Hughes, E.L., Company Building, 209 E. Main St., Louisville, 16000498
Seventh Street School, 1512 S. 7th St., Louisville, 16000499

Kenton County

Independence Historic District, Portions of Madison & McCullum Pikes, Independence, 16000500
Peaselburg Neighborhood Historic District, W. 16th, Holman, W. 19th & Russell Sts., Covington, 16000501

Laurel County

London Tuberculosis Hospital (Kentucky State Tuberculosis Hospitals, 1946–1950 MPS), 85 State Police Rd., London, 16000503

Mason County

Maysville Downtown Historic District (Boundary Increase), W. 2nd, Sutton, Market, Limestone, W. 4th & E. 4th Sts., Maysville, 16000502

McCracken County

Shawnee Steam Plant, 7900 Metropolis Lake Rd., West Paducah, 16000504

Oldham County

Johnson's Landing House and Farm, 2300 Rose Island Rd., Goshen, 16000505
Woodland, 3008 Ann Trese Cove, Crestwood, 16000506

MICHIGAN

Ingham County

Pulver Brothers Filling Station, 127 W. Grand River Ave., Lansing, 16000507

Ionia County

Portland High School, 306 Brush St., Portland, 16000508

Otsego County

Quick, James A. and Lottie J. (Congdon), House, 120 N. Center St., Gaylord, 16000509

Shiawassee County

Lincoln School, 120 Michigan Ave., Owosso, 16000510

MINNESOTA

Hennepin County

Grain Belt Beer Sign, 4 Island Ave. W., Minneapolis, 16000511

St. Louis County

Chisholm Commercial Historic District, W. Lake St. between Central Ave. N. & S. & 4th Ave., NW. & SW., the E. side of Central Ave. N. & S. between 1st St. NE., Chisholm, 16000512

MISSOURI

Jackson County

Belmont Hotel, 911 E. Linwood Blvd., Kansas City, 16000513

NEBRASKA

Gage County

First Trinity Lutheran Church, 11668 W. NE 4, Beatrice, 16000514

Lancaster County

Sky Park Manor, 1301 Lincoln Mall, Lincoln, 16000515

Washington County

Gottsch Farmstead, 17201 Dutch Hall Rd., Bennington, 16000516

PENNSYLVANIA

Union County

Spangler, George Christian and Anna Catherine, Farm, 1175 Wildwood, Mifflinburg, 16000517

WISCONSIN

Dane County

University of Wisconsin Arboretum, 1207 Seminole Hwy., Madison, 16000518

Racine County

Walker Manufacturing Company—Ajax Plant, 1520 Clark St., Racine, 16000519

WYOMING

Teton County

Alpenhof Lodge (Tourist Accommodations in Teton County, Wyoming MPS), 3255 W. Village Dr., Teton Village, 16000520

A request for removal has been received for the following resources:

MINNESOTA

Anoka County

Richardson Barn, 22814 Sunrise Rd., NE., East Bethel, 79001191

SOUTH CAROLINA

Jasper County

Grays Consolidated High School, US 278, Grays, 07000986

Lee County

Bishopville High School, 600 N. Main St., Bishopville, 04001087

Marion County

Old Brick Warehouse, Main and Wine Sts., Mullins, 84003828
Teasley, J.C., House, 131 E. Wine St., Mullins, 01000609

Authority: 60.13 of 36 CFR part 60.

Dated: June 30, 2016.

J. Paul Loether,

Chief, National Register of Historic Places/ National Historic Landmarks Program.

[FR Doc. 2016–16712 Filed 7–14–16; 8:45 am]

BILLING CODE 4312–51–P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Cooperative Research Group on Development of a Predictive Model for Corrosion-Fatigue of Materials in Sour Environment

Notice is hereby given that, on June 9, 2016, pursuant to section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (“the Act”), Southwest Research Institute—Cooperative Research Group on Development of a Predictive Model for Corrosion-Fatigue of Materials in Sour Environment (“Model-CFM”) has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act’s provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, Tubos De Acero De Mexico S.A., Veracruz, MEXICO; and Vallourec Mannesmann Oil & Gas France, Aulnoye-Aymeries, FRANCE, have withdrawn as parties to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and Model-CFM intends to file additional written notifications disclosing all changes in membership.

On May 17, 2011, Model-CFM filed its original notification pursuant to section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to section 6(b) of the Act on July 7, 2011 (76 FR 39901).

The last notification was filed with the Department on September 26, 2011. A notice was published in the **Federal Register** pursuant to section 6(b) of the Act on October 26, 2011 (76 FR 66325).

Patricia A. Brink,

Director of Civil Enforcement, Antitrust Division.

[FR Doc. 2016–16778 Filed 7–14–16; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Notice of Lodging Proposed Consent Order

In accordance with Departmental Policy, 28 CFR 50.7, notice is hereby given that a proposed consent order in *United States, et al.* v. *Hubenka and LeClair Irrigation District,* Civil No. 10–cv–0093–ABJ, was lodged with the United States District Court for the District of Wyoming on July 11, 2016.

This proposed Order Amending Memorandum Opinion Filed October 22, 2014, concerns a complaint filed by the United States against John Hubenka and LeClair Irrigation District under Sections 309(b) and (d) of the Clean Water Act, 33 U.S.C. 1319(b) and (d), to obtain injunctive relief from both Defendants and impose civil penalties on Mr. Hubenka for violating the Clean Water Act by discharging pollutants without a permit into waters of the United States. The Northern Arapaho Tribe and the Eastern Shoshone Tribe intervened as Plaintiffs. The proposed Order Amending Memorandum Opinion Filed October 22, 2014, resolves these allegations by, among other things, requiring the Defendants to restore the impacted areas and requiring Mr. Hubenka to pay a civil penalty.

The Department of Justice will accept written comments relating to this proposed Order Amending Memorandum Opinion Filed October 22, 2014, for thirty (30) days from the date of publication of this Notice. Please address comments to Alan D. Greenberg, Senior Attorney, United States Department of Justice, Environment and Natural Resources Division, Environmental Defense Section, 999 18th Street, Suite 370—South Terrace, Denver, CO 80202 and refer to *United States, et al.* v. *Hubenka and LeClair Irrigation District,* DJ # 90–5–1–1–18408.

The proposed Order Amending Memorandum Opinion Filed October 22, 2014, may be examined at the Clerk’s Office, United States District Court for the District of Wyoming, 2120 Capitol Avenue, Room 2131, Cheyenne, WY 82001. In addition, the Master Settlement Agreement, including the proposed Order Amending Memorandum Opinion Filed October 22, 2014, may be examined electronically at *http://www.justice.gov/enrd/Consent_Decrees.html.*

Cherie L. Rogers,

Assistant Section Chief, Environmental Defense Section, Environment and Natural Resources Division.

[FR Doc. 2016–16772 Filed 7–14–16; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF JUSTICE

Office of Justice Programs

[OJP (NIJ) Docket No. 1715]

Publication of Offender Tracking System Standard, NIJ Standard-1004.00, and Request for Expressions of Interest From Manufacturers and Conformity Assessment Bodies

AGENCY: National Institute of Justice, Justice.

ACTION: Notice.

SUMMARY: The National Institute of Justice (NIJ) announces publication of *Offender Tracking System Standard,* NIJ Standard-1004.00. The document can be found here: *https://www.ncjrs.gov/pdffiles1/nij/249810.pdf.* NIJ is currently exploring strategies for conformity assessment of offender tracking systems in accordance with this new standard. Manufacturers interested in testing their products for conformance to the new standard are invited to review the standard and provide an expression of interest to the point of contact listed below. Likewise, conformity assessment bodies, such as laboratories, certification bodies, inspection bodies, and accreditation bodies, interested in participating in conformity assessment activities are invited to review the standard and provide an expression of interest to the point of contact listed below. Any feedback regarding this standard should also be directed to the point of contact listed below. For more information about NIJ standards, please visit *http://nij.gov/standards.*

FOR FURTHER INFORMATION CONTACT: Jack Harne, by telephone at (202) 598–9412 [Note: this is not a toll-free telephone number], or by email at *jack.harne@usdoj.gov.*

Nancy Rodriguez,

Director, National Institute of Justice.

[FR Doc. 2016–16760 Filed 7–14–16; 8:45 am]

BILLING CODE 4410–18–P

DEPARTMENT OF JUSTICE

Office of Justice Programs

[OJP (NIJ) Docket No. 1717]

Draft Baseline Specifications for Law Enforcement Service Pistols With Security Technology

AGENCY: National Institute of Justice, Justice.

ACTION: Notice and request for comments.

SUMMARY: The National Institute of Justice (NIJ) seeks feedback from the public on a draft document that defines generic baseline specifications for law enforcement service pistols with additional technology to enhance the security of the firearms, published here: *http://nij.gov/topics/technology/firearms/pages/welcome.aspx.*

DATES: Comments must be received by 5 p.m. Eastern Time on September 13, 2016.

How to Respond and What to Include: The draft baseline specifications document can be found here: *http://nij.gov/topics/technology/firearms/pages/welcome.aspx.* To submit comments, please send an email to *gunsafetytechnology@usdoj.gov.* Please indicate the page number, section number, and the line number associated with each comment. Comments may also be provided as a markup of the Word document. Please provide contact information with the submission of comments. Address comments to Mark Greene, Office of Science and Technology, National Institute of Justice.

FOR FURTHER INFORMATION CONTACT: Mark Greene, Office of Science and Technology, National Institute of Justice, 810 7th Street NW., Washington, DC 20531; telephone number: (202) 598–9412; email address: *mark.greene2@usdoj.gov.*

SUPPLEMENTARY INFORMATION: On April 29, 2016, the U.S. Departments of Justice (DOJ), Homeland Security (DHS), and Defense (DoD) submitted a joint report to the President outlining a strategy to expedite deployment of gun safety technology, found here: *https://www.whitehouse.gov/sites/default/files/docs/final_report-smart_gun_report.pdf.*

The report was published in response to Presidential Memorandum, *Promoting Smart Gun Technology,* found here: *https://www.whitehouse.gov/the-press-office/2016/01/05/memorandum-promoting-smart-gun-technology.* The report described the potential benefits of advanced gun safety technology, but noted that additional work was required before this technology is ready for widespread adoption by law enforcement agencies. In particular, the report stressed the importance of integrating this technology into a firearm's design without compromising the reliability, durability, and accuracy that officers expect from their service weapons.

To address these issues, the report called on law enforcement agencies to develop "baseline specifications," which would outline the agencies' operational requirements for any firearms equipped with gun safety technology. By developing baseline specifications, federal, state, and municipal law enforcement agencies can make clear to private manufacturers what they expect from this technology.

DOJ and DHS recently assembled a working group of experts in firearms technology to identify operational needs and prepare a draft document that defines generic baseline specifications for law enforcement service pistols with additional technology to enhance the security of firearms. The additional security specifications that may be addressed by smart gun technology are distinguished from more familiar firearm safety mechanisms. The distinction between safety and security can be nuanced, and the additional security specifications may also function as safety features under certain circumstances. However, this distinction forms the basis of the use of the different terminology.

The working group was led by NIJ and was comprised of subject matter experts from various federal law enforcement agencies. The pistols defined by this document are semi-automatic, recoil-operated, magazine-fed, striker-fired, and fire 9 mm Luger or .40 S&W ammunition. The information detailed in this document is informed in part by specifications enumerated in recent handgun solicitations by the Federal Bureau of Investigation (FBI) and Immigration of Customs Enforcement (ICE), which are publicly available on FedBizOpps (*http://www.fbo.gov*) under solicitation numbers RFP–OSCU–DSU1503 and HSCEMS–16–R–00003, respectively.

Jennifer Scherer,

Deputy Director, National Institute of Justice.

[FR Doc. 2016–16759 Filed 7–14–16; 8:45 am]

BILLING CODE 4410–18–P

LEGAL SERVICES CORPORATION

Sunshine Act Meeting: Board of Directors and Its Six Committees

AGENCY: Legal Services Corporation.

ACTION: Change notice.

SUMMARY: On July 12, 2016, the Legal Services Corporation (LSC) published a notice in the **Federal Register** (81 FR 45177) titled "Board of Directors and its Six Committees will meet on July 17–19, 2016, EDT". The Operations and Regulations Committee scheduled to meet on July 18, 2016 at 8:30 a.m., EDT, has added another item to the agenda as line item #3; all other items remain consecutively the same. This document changes the notice by revising the Operations and Regulations Committee agenda by adding another item as line item #3.

Changes in the Meeting: Operations and Regulations Committee agenda revised to add the following.

3. Briefing on acquisitions management
    - Ron Flagg, General Counsel
    - Rebecca Weir, Senior Assistant General Counsel

DATES: This change is effective July 13, 2016.

FOR FURTHER INFORMATION CONTACT: Katherine Ward, Executive Assistant to the Vice President for Legal Affairs and General Counsel, Legal Services Corporation, 3333 K Street NW., Washington, DC 20007; (202) 295–1500; *kward@lsc.gov.*

Dated: July 13, 2016.

Katherine Ward,

Executive Assistant to the Vice President for Legal Affairs and General Counsel.

[FR Doc. 2016–16939 Filed 7–13–16; 4:15 pm]

BILLING CODE 7050–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2015–0220]

Seismic Design Classification for Nuclear Power Plants

AGENCY: Nuclear Regulatory Commission.

ACTION: Regulatory guide; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing Revision 5 of Regulatory Guide (RG) 1.29, "Seismic Design Classification for Nuclear Power Plants." This RG describes a method that the staff of the NRC considers acceptable for use in identifying and classifying those features of light-water-reactor (LWR) nuclear power plants that must be designed to withstand the

effects of the safe-shutdown earthquake (SSE).

ADDRESSES: Please refer to Docket ID NRC–2015–0220 when contacting the NRC about the availability of information regarding this document. You may obtain publically-available information related to this document, using the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2015–0220. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.* For technical questions, contact the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Document collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select "ADAMS Public Documents" and then select "*Begin Web-based ADAMS Search.*" For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in this document. Revision 5 of RG 1.29, is available in ADAMS under Accession No. ML16118A148. The regulatory analysis is also available in ADAMS under Accession No. ML15131A397.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

Regulatory guides are not copyrighted, and NRC approval is not required to reproduce them.

FOR FURTHER INFORMATION CONTACT: Yiu Law, Office of New Reactors, telephone: 301–415–0523, email: *Yiu.Law@nrc.gov,* and Edward O'Donnell, Office of Nuclear Regulatory Research, telephone: 301–415–3317, email: *Edward.O'Donnell@nrc.gov.* Both are staff members of the U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

SUPPLEMENTARY INFORMATION:

I. Introduction

The NRC is issuing a revision to an existing guide in the NRC's "Regulatory Guide" series. This series was developed to describe and make available to the public information regarding methods that are acceptable to the NRC staff for implementing specific parts of the agency's regulations, techniques that the staff uses in evaluating specific issues or postulated events, and data that the staff needs in its review of applications for permits and licenses.

Revision 5 of RG 1.29 was issued with a temporary identification of Draft Regulatory Guide, DG–1315. Revision 5 of RG 1.29 contains minor non-substantive changes that do not present new regulatory requirements, but clarifies content in Section C, "Staff Regulatory Guidance," by (1) addition of a reference to the definition of the reactor coolant pressure boundary in section 50.2 of title 10 of the *Code of Federal Regulations* (10 CFR), and (2) a reorganization of systems and subsystems to add clarity to the staff guidance. In addition, it adds a reference to a related international standard, and it was reformatted to align with the current program guidance for regulatory guides.

II. Additional Information

The DG–1315 was published in the **Federal Register** (80 FR 55878) on September 17, 2015 for a 60-day public comment period. Public comments on DG–1315 and the staff's responses to the public comments are available in ADAMS under Accession No. ML16118A149.

III. Backfitting and Issue Finality

The RG 1.29 describes a method that the staff of the NRC considers acceptable for use in identifying and classifying those features of LWR nuclear power plants that must be designed to withstand the effects of the SSE. Issuance of this RG does not constitute backfitting as defined in 10 CFR 50.109 (the Backfit Rule) and is not otherwise inconsistent with the issue finality provisions in 10 CFR part 52. As discussed in the "Implementation" section of this RG, the NRC has no current intention to impose this RG on holders of current operating licenses or combined licenses.

This RG may be applied to applications for operating licenses, combined licenses, early site permits, and certified design rules docketed by the NRC as of the date of issuance of the final regulatory guide, as well as future applications submitted after the issuance of the regulatory guide. Such action would not constitute backfitting as defined in the Backfit Rule or be otherwise inconsistent with the applicable issue finality provision in 10 CFR part 52, inasmuch as such applicants or potential applicants are not within the scope of entities protected by the Backfit Rule or the relevant issue finality provisions in part 52.

Dated at Rockville, Maryland, this 8th day of July 2016.

For the Nuclear Regulatory Commission.

Carol E. Moyer,

Acting Chief, Regulatory Guidance and Generic Issues Branch, Division of Engineering, Office of Nuclear Regulatory Research.

[FR Doc. 2016–16767 Filed 7–14–16; 8:45 am]

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NUCLEAR REGULATORY COMMISSION

[Docket No. 50–400; NRC–2016–0136]

Duke Energy Progress, Inc.; Shearon Harris Nuclear Power Plant, Unit 1; Surveillance Frequency Control Program

AGENCY: Nuclear Regulatory Commission.

ACTION: License amendment application; opportunity to comment, request a hearing, and petition for leave to intervene; order.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is considering issuance of an amendment to Facility Operating License No. NPF–63, issued to Duke Energy Progress, Inc., for operation of the Shearon Harris Nuclear Power Plant, Unit 1. The amendment would revise the Shearon Harris Nuclear Power Plant, Unit 1, Technical Specifications (TSs) by relocating specific surveillance frequencies to a licensee-controlled program with the implementation of Nuclear Energy Institute (NEI) 04–10, "Risk-Informed Technical Specifications Initiative 5b, Risk-Informed Method for Control of Surveillance Frequencies." Additionally, the change would add a new program, the Surveillance Frequency Control Program, to TS Section 6, "Administrative Controls." The amendment application contains sensitive unclassified non-safeguards information (SUNSI).

DATES: Submit comments by August 15, 2016. A requests for a hearing or petition for leave to intervene must be filed by September 13, 2016. Any potential party as defined in § 2.4 of title 10 of the *Code of Federal Regulations* (10 CFR), who believes access to SUNSI is necessary to respond to this notice must request document access by September 13, 2016.

ADDRESSES: You may submit comments by any of the following methods (unless this document describes a different method for submitting comments on a specific subject):

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2016–0136. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Mail comments to:* Cindy Bladey, Office of Administration, Mail Stop: OWFN–12–H08, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

For additional direction on obtaining information and submitting comments, see "Obtaining Information and Submitting Comments" in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Dennis Galvin, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington DC 20555–0001; telephone: 301–415–6256, email: *Dennis.Galvin@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2016–0136 when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2016–0136.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select "*ADAMS Public Documents*" and then select "*Begin Web-based ADAMS Search.*" For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in the **SUPPLEMENTARY INFORMATION** section.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

B. Submitting Comments

Please include Docket ID NRC–2016–0136 in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC posts all comment submissions at *http://www.regulations.gov* as well as entering the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment submissions into ADAMS.

II. Introduction

The NRC is considering issuance of an amendment to Facility Operating License No. NPF–63, issued to Duke Energy Progress, Inc., for operation of the Shearon Harris Nuclear Power Plant, Unit 1, located in Wake and Chatham Counties, North Carolina.

The amendment request was submitted August 18, 2015, and supplemented by letters dated September 29, 2015, February 5, 2016, April 28, 2016, and May 19, 2016. Publicly-available versions are in ADAMS under Accession Nos. ML15236A265 (Package), ML15272A443, ML16036A091, ML16119A326, and ML16141A048, respectively. The supplemental letters to this amendment request dated February 5 and April 28, 2016, contain SUNSI. The NRC staff previously made a proposed determination that the amendment request dated August 18, 2015, involves no significant hazards considerations (80 FR 76319; December 8, 2015). Subsequently, by letter dated May 19, 2016, the licensee provided additional information that expanded the scope of the amendment request as originally noticed. Accordingly, this notice supersedes the previous notice in its entirety.

The amendment would revise the Shearon Harris Nuclear Power Plant, Unit 1, TSs by relocating specific surveillance frequencies to a licensee-controlled program with the implementation of NEI 04–10, "Risk-Informed Technical Specifications Initiative 5b, Risk-Informed Method for Control of Surveillance Frequencies" (ADAMS Accession No. ML071360456). Additionally, the change would add a new program, the Surveillance Frequency Control Program, to TS Section 6, "Administrative Controls" (ADAMS Accession No. ML052860283). The changes are consistent with the NRC-approved Technical Specification Task Force (TSTF) Improved Standard Technical Specifications Change Traveler–425, Revision 3, "Relocate Surveillance Frequencies to Licensee Control—RITSTF [Risk-Informed Technical Specification Task Force] Initiative 5b" (ADAMS Accession No. ML090850642). In the supplement dated May 19, 2016, the licensee requested additional surveillance frequencies be relocated to a licensee-controlled program.

Before any issuance of the proposed license amendment, the NRC will need to make the findings required by the Atomic Energy Act of 1954, as amended (the Act), and the NRC's regulations.

The NRC has made a proposed determination that the license amendment request involves no significant hazards consideration. Under the NRC's regulations in 10 CFR 50.92, this means that operation of the facility in accordance with the proposed amendment would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety. As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed change involve a significant increase in the probability or consequences of any accident previously evaluated?

Response: No.

The proposed change relocates the specified frequencies for periodic surveillance requirements to licensee control under a new Surveillance Frequency Control Program. Surveillance frequencies are not an initiator to any accident previously evaluated. As a result, the probability of any accident previously evaluated is not significantly increased. The systems and components required by the technical specifications for which the surveillance frequencies are relocated are still required to be operable, meet the acceptance criteria for the surveillance requirements, and be capable of performing any mitigation function assumed in the accident analysis. As a result, the consequences of any accident previously evaluated are not significantly increased.

2. Does the proposed change create the possibility of a new or different kind of accident from any previously evaluated?

Response: No.

No new or different accidents result from utilizing the proposed change. The changes do not involve a physical alteration of the plant (*i.e.*, no new or different type of equipment will be installed) or a change in the methods governing normal plant operation. In addition, the changes do not impose any new or different requirements. The changes do not alter assumptions made in the safety analysis. The proposed changes are consistent with the safety analysis assumptions and current plant operating practice.

Therefore, the proposed changes do not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the proposed change involve a significant reduction in the margin of safety?

Response: No.

The design, operation, testing methods, and acceptance criteria for systems, structures, and components (SSCs), specified in applicable codes and standards (or alternatives approved for use by the NRC) will continue to be met as described in the plant licensing basis (including the final safety analysis report and bases to TS), since these are not affected by changes to the surveillance frequencies. Similarly, there is no impact to safety analysis acceptance criteria as described in the plant licensing basis. To evaluate a change in the relocated surveillance frequency, Duke Energy will perform a probabilistic risk evaluation using the guidance contained in NRC approved NEI 04–10, Revision 1, in accordance with the TS Surveillance Frequency Control Program. NEI 04–10, Revision 1, methodology provides reasonable acceptance guidelines and methods for evaluating the risk increase of proposed changes to surveillance frequencies consistent with Regulatory Guide 1.177.

Therefore, the proposed changes do not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the license amendment request involves a no significant hazards consideration.

The NRC is seeking public comments on this proposed determination that the license amendment request involves no significant hazards consideration. Any comments received within 30 days after the date of publication of this notice will be considered in making any final determination.

Normally, the Commission will not issue the amendment until the expiration of 60 days after the date of publication of this notice. The Commission may issue the license amendment before expiration of the 60-day notice period if the Commission concludes the amendment involves no significant hazards consideration. In addition, the Commission may issue the amendment prior to the expiration of the 30-day comment period if circumstances change during the 30-day comment period such that failure to act in a timely way would result, for example, in derating or shutdown of the facility. If the Commission takes action prior to the expiration of either the comment period or the notice period, it will publish in the **Federal Register** a notice of issuance. If the Commission makes a final no significant hazards consideration determination, any hearing will take place after issuance. The Commission expects that the need to take this action will occur very infrequently.

III. Opportunity To Request a Hearing and Petition for Leave To Intervene

Within 60 days after the date of publication of this notice, any person(s) whose interest may be affected by this action may file a request for a hearing and a petition to intervene with respect to issuance of the amendment to the subject facility operating license or combined license. Requests for a hearing and a petition for leave to intervene shall be filed in accordance with the Commission's "Agency Rules of Practice and Procedure" in 10 CFR part 2. Interested person(s) should consult a current copy of 10 CFR 2.309, which is available at the NRC's PDR, located at One White Flint North, Room O1–F21, 11555 Rockville Pike (first floor), Rockville, Maryland 20852. The NRC's regulations are accessible electronically from the NRC Library on the NRC's Web site at *http://www.nrc.gov/reading-rm/doc-collections/cfr/*. If a request for a hearing or petition for leave to intervene is filed within 60 days, the Commission or a presiding officer designated by the Commission or by the Chief Administrative Judge of the Atomic Safety and Licensing Board Panel, will rule on the request and/or petition; and the Secretary or the Chief Administrative Judge of the Atomic Safety and Licensing Board will issue a notice of a hearing or an appropriate order.

As required by 10 CFR 2.309, a petition for leave to intervene shall set forth with particularity the interest of the petitioner in the proceeding, and how that interest may be affected by the results of the proceeding. The petition should specifically explain the reasons why intervention should be permitted with particular reference to the following general requirements: (1) The name, address, and telephone number of the requestor or petitioner; (2) the nature of the requestor's/petitioner's right under the Act to be made a party to the proceeding; (3) the nature and extent of the requestor's/petitioner's property, financial, or other interest in the proceeding; and (4) the possible effect of any decision or order which may be entered in the proceeding on the requestor's/petitioner's interest. The petition must also set forth the specific contentions which the requestor/petitioner seeks to have litigated at the proceeding.

Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the requestor/petitioner shall provide a brief explanation of the bases for the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the requestor/petitioner intends to rely in proving the contention at the hearing. The requestor/petitioner must also provide references to those specific sources and documents of which the petitioner is aware and on which the requestor/petitioner intends to rely to establish those facts or expert opinion. The petition must include sufficient information to show that a genuine dispute exists with the applicant on a material issue of law or fact. Contentions shall be limited to matters within the scope of the amendment under consideration. The contention must be one which, if proven, would entitle the requestor/petitioner to relief. A requestor/petitioner who fails to satisfy these requirements with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing with respect to resolution of that person's admitted contentions, including the opportunity to present evidence and to submit a cross-examination plan for cross-examination of witnesses, consistent with NRC's regulations, policies and procedures.

Petitions for leave to intervene must be filed no later than 60 days from the date of publication of this notice. Requests for hearing, petitions for leave to intervene, and motions for leave to file new or amended contentions that are filed after the 60-day deadline will not be entertained absent a determination by the presiding officer that the filing demonstrates good cause by satisfying the three factors in 10 CFR 2.309(c)(1)(i)–(iii).

If a hearing is requested, and the Commission has not made a final determination on the issue of no significant hazards consideration, the Commission will make a final determination on the issue of no significant hazards consideration. The final determination will serve to decide when the hearing is held. If the final determination is that the amendment request involves no significant hazards consideration, the Commission may issue the amendment and make it immediately effective, notwithstanding the request for a hearing. Any hearing held would take place after issuance of the amendment. If the final determination is that the amendment request involves a significant hazards consideration, then any hearing held would take place before the issuance of any amendment unless the Commission finds an imminent danger to the health or safety of the public, in which case it will issue an appropriate order or rule under 10 CFR part 2.

A State, local governmental body, Federally-recognized Indian Tribe, or agency thereof, may submit a petition to the Commission to participate as a party under 10 CFR 2.309(h)(1). The petition should state the nature and extent of the petitioner's interest in the proceeding. The petition should be submitted to the Commission by September 13, 2016. The petition must be filed in accordance with the filing instructions in the "Electronic Submissions (E-Filing)" section of this document, and should meet the requirements for petitions for leave to intervene set forth in this section, except that under § 2.309(h)(2) a State, local governmental body, or Federally-recognized Indian Tribe, or agency thereof does not need to address the standing requirements in 10 CFR 2.309(d) if the facility is located within its boundaries. A State, local governmental body, Federally-recognized Indian Tribe, or agency thereof may also have the opportunity to participate under 10 CFR 2.315(c).

If a hearing is granted, any person who does not wish, or is not qualified, to become a party to the proceeding may, in the discretion of the presiding officer, be permitted to make a limited appearance pursuant to the provisions of 10 CFR 2.315(a). A person making a limited appearance may make an oral or written statement of position on the issues, but may not otherwise participate in the proceeding. A limited appearance may be made at any session of the hearing or at any prehearing conference, subject to the limits and conditions as may be imposed by the presiding officer. Persons desiring to make a limited appearance are requested to inform the Secretary of the Commission by September 13, 2016.

IV. Electronic Submissions (E-Filing)

All documents filed in NRC adjudicatory proceedings, including a request for hearing, a petition for leave to intervene, any motion or other document filed in the proceeding prior to the submission of a request for hearing or petition to intervene, and documents filed by interested governmental entities participating under 10 CFR 2.315(c), must be filed in accordance with the NRC's E-Filing rule (72 FR 49139; August 28, 2007). The E-Filing process requires participants to submit and serve all adjudicatory documents over the internet, or in some cases to mail copies on electronic storage media. Participants may not submit paper copies of their filings unless they seek an exemption in accordance with the procedures described below.

To comply with the procedural requirements of E-Filing, at least 10 days prior to the filing deadline, the participant should contact the Office of the Secretary by email at *hearing.docket@nrc.gov,* or by telephone at 301–415–1677, to request (1) a digital identification (ID) certificate, which allows the participant (or its counsel or representative) to digitally sign documents and access the E-Submittal server for any proceeding in which it is participating; and (2) advise the Secretary that the participant will be submitting a request or petition for hearing (even in instances in which the participant, or its counsel or representative, already holds an NRC-issued digital ID certificate). Based upon this information, the Secretary will establish an electronic docket for the hearing in this proceeding if the Secretary has not already established an electronic docket.

Information about applying for a digital ID certificate is available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals/getting-started.html.* System requirements for accessing the E-Submittal server are detailed in the NRC's "Guidance for Electronic Submission," which is available on the agency's public Web site at *http://www.nrc.gov/site-help/e-submittals.html.* Participants may attempt to use other software not listed on the Web site, but should note that the NRC's E-Filing system does not support unlisted software, and the NRC Meta System Help Desk will not be able to offer assistance in using unlisted software.

If a participant is electronically submitting a document to the NRC in accordance with the E-Filing rule, the participant must file the document using the NRC's online, Web-based submission form. In order to serve documents through the Electronic Information Exchange System, users will be required to install a Web browser plug-in from the NRC's Web site. Further information on the Web-based submission form, including the installation of the Web browser plug-in, is available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals.html.*

Once a participant has obtained a digital ID certificate and a docket has been created, the participant can then submit a request for hearing or petition for leave to intervene. Submissions should be in Portable Document Format (PDF) in accordance with NRC guidance available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals.html.* A filing is considered complete at the time the documents are submitted through the NRC's E-Filing system. To be timely, an electronic filing must be submitted to the E-Filing system no later than 11:59 p.m. Eastern Time on the due date. Upon receipt of a transmission, the E-Filing system time-stamps the document and sends the submitter an email notice confirming receipt of the document. The E-Filing system also distributes an email notice that provides access to the document to the NRC's Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the documents on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before a hearing request/petition to intervene is filed so that they can obtain access to the document via the E-Filing system.

A person filing electronically using the NRC's adjudicatory E-Filing system may seek assistance by contacting the NRC Meta System Help Desk through the "Contact Us" link located on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals.html,* by email to *MSHD.Resource@nrc.gov,* or by a toll-free call at 1–866–672–7640. The NRC Meta System Help Desk is available between 8 a.m. and 8 p.m., Eastern Time, Monday through Friday, excluding government holidays.

Participants who believe that they have a good cause for not submitting documents electronically must file an exemption request, in accordance with 10 CFR 2.302(g), with their initial paper filing requesting authorization to continue to submit documents in paper format. Such filings must be submitted by: (1) First class mail addressed to the Office of the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemaking and Adjudications Staff; or (2) courier, express mail, or expedited delivery service to the Office of the Secretary, Sixteenth Floor, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852, Attention: Rulemaking and Adjudications Staff. Participants filing a document in this manner are responsible for serving the document on all other participants. Filing is considered complete by first-class mail as of the time of deposit in the mail, or by courier, express mail, or expedited delivery service upon depositing the document with the provider of the service. A presiding officer, having granted an exemption request from using E-Filing, may require a participant or party to use E-Filing if the presiding officer subsequently determines that the reason for granting the exemption from use of E-Filing no longer exists.

Documents submitted in adjudicatory proceedings will appear in the NRC's electronic hearing docket which is available to the public at *http://ehd1.nrc.gov/ehd/,* unless excluded pursuant to an order of the Commission, or the presiding officer. Participants are requested not to include personal privacy information, such as social security numbers, home addresses, or home phone numbers in their filings, unless an NRC regulation or other law requires submission of such information. However, in some instances, a request to intervene will require including information on local residence in order to demonstrate a proximity assertion of interest in the proceeding. With respect to copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, participants are requested not to include copyrighted materials in their submission.

For further details with respect to this action, see the application for license amendment dated August 18, 2015, as supplemented on September 29, 2015, February 5, 2016, April 28, 2016, and May 19, 2016.

Attorney for licensee: Kathryn B. Nolan, Associate General Counsel, Duke Energy Corporation, 550 South Tyron Street, Mail Code DEC45A, Charlotte, NC 28202.

NRC Acting Branch Chief: Tracy J. Orf.

Order Imposing Procedures for Access to Sensitive Unclassified Non-Safeguards Information for Contention Preparation

Duke Energy Progress, Inc., Docket No. 50–400, Shearon Harris Nuclear Power Plant, Unit 1, Wake and Chatham Counties, North Carolina

A. This Order contains instructions regarding how potential parties to this proceeding may request access to documents containing SUNSI.

B. Within 10 days after publication of this notice of hearing and opportunity to petition for leave to intervene, any potential party who believes access to SUNSI is necessary to respond to this notice may request such access. A "potential party" is any person who intends to participate as a party by demonstrating standing and filing an admissible contention under 10 CFR 2.309. Requests for access to SUNSI submitted later than 10 days after publication of this notice will not be considered absent a showing of good cause for the late filing, addressing why the request could not have been filed earlier.

C. The requester shall submit a letter requesting permission to access SUNSI to the Office of the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemakings and Adjudications Staff, and provide a copy to the Associate General Counsel for Hearings, Enforcement and Administration, Office of the General Counsel, Washington, DC 20555–0001. The expedited delivery or courier mail address for both offices is: U.S. Nuclear Regulatory Commission, 11555 Rockville Pike, Rockville, Maryland 20852. The email address for the Office of the Secretary and the Office of the General Counsel are *Hearing.Docket@nrc.gov* and *OGCmailcenter@nrc.gov,* respectively.[1] The request must include the following information:

(1) A description of the licensing action with a citation to this **Federal Register** notice;

(2) The name and address of the potential party and a description of the potential party's particularized interest that could be harmed by the action identified in C.(1); and

(3) The identity of the individual or entity requesting access to SUNSI and the requester's basis for the need for the information in order to meaningfully participate in this adjudicatory proceeding. In particular, the request must explain why publicly-available versions of the information requested would not be sufficient to provide the basis and specificity for a proffered contention.

D. Based on an evaluation of the information submitted under paragraph C.(3) the NRC staff will determine within 10 days of receipt of the request whether:

(1) There is a reasonable basis to believe the petitioner is likely to establish standing to participate in this NRC proceeding; and

(2) The requestor has established a legitimate need for access to SUNSI.

E. If the NRC staff determines that the requestor satisfies both D.(1) and D.(2) above, the NRC staff will notify the requestor in writing that access to SUNSI has been granted. The written notification will contain instructions on how the requestor may obtain copies of the requested documents, and any other conditions that may apply to access to those documents. These conditions may include, but are not limited to, the signing of a Non-Disclosure Agreement or Affidavit, or Protective Order[2] setting forth terms and conditions to prevent the unauthorized or inadvertent disclosure of SUNSI by each individual who will be granted access to SUNSI.

F. Filing of Contentions. Any contentions in these proceedings that are based upon the information received as a result of the request made for SUNSI must be filed by the requestor no later than 25 days after the requestor is granted access to that information. However, if more than 25 days remain between the date the petitioner is granted access to the information and the deadline for filing all other contentions (as established in the notice of hearing or opportunity for hearing), the petitioner may file its SUNSI contentions by that later deadline. This provision does not extend the time for filing a request for a hearing and petition to intervene, which must comply with the requirements of 10 CFR 2.309.

G. Review of Denials of Access.

(1) If the request for access to SUNSI is denied by the NRC staff after a determination on standing and need for access, the NRC staff shall immediately notify the requestor in writing, briefly

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[1] While a request for hearing or petition to intervene in this proceeding must comply with the filing requirements of the NRC's "E-Filing Rule," the initial request to access SUNSI under these procedures should be submitted as described in this paragraph.

[2] Any motion for Protective Order or draft Non-Disclosure Affidavit or Agreement for SUNSI must be filed with the presiding officer or the Chief Administrative Judge if the presiding officer has not yet been designated, within 30 days of the deadline for the receipt of the written access request.

stating the reason or reasons for the denial.

(2) The requester may challenge the NRC staff's adverse determination by filing a challenge within 5 days of receipt of that determination with: (a) The presiding officer designated in this proceeding; (b) if no presiding officer has been appointed, the Chief Administrative Judge, or if he or she is unavailable, another administrative judge, or an administrative law judge with jurisdiction pursuant to 10 CFR 2.318(a); or (c) officer if that officer has been designated to rule on information access issues.

H. Review of Grants of Access. A party other than the requester may challenge an NRC staff determination granting access to SUNSI whose release would harm that party's interest independent of the proceeding. Such a challenge must be filed with the Chief Administrative Judge within 5 days of the notification by the NRC staff of its grant of access.

If challenges to the NRC staff determinations are filed, these procedures give way to the normal process for litigating disputes concerning access to information. The availability of interlocutory review by the Commission of orders ruling on such NRC staff determinations (whether granting or denying access) is governed by 10 CFR 2.311.[3]

I. The Commission expects that the NRC staff and presiding officers (and any other reviewing officers) will consider and resolve requests for access to SUNSI, and motions for protective orders, in a timely fashion in order to minimize any unnecessary delays in identifying those petitioners who have standing and who have propounded contentions meeting the specificity and basis requirements in 10 CFR part 2. Attachment 1 to this Order summarizes the general target schedule for processing and resolving requests under these procedures.

It is so Ordered.

Dated at Rockville, Maryland, this 11th day of July 2016.

For the Nuclear Regulatory Commission.

Andrew L. Bates,

Acting, Secretary of the Commission.

ATTACHMENT 1—GENERAL TARGET SCHEDULE FOR PROCESSING AND RESOLVING REQUESTS FOR ACCESS TO SENSITIVE UNCLASSIFIED NON-SAFEGUARDS INFORMATION IN THIS PROCEEDING

Day	Event/activity
0	Publication of **Federal Register** notice of hearing and opportunity to petition for leave to intervene, including order with instructions for access requests.
10	Deadline for submitting requests for access to Sensitive Unclassified Non-Safeguards Information (SUNSI) with information: Supporting the standing of a potential party identified by name and address; describing the need for the information in order for the potential party to participate meaningfully in an adjudicatory proceeding.
60	Deadline for submitting petition for intervention containing: (i) Demonstration of standing; and (ii) all contentions whose formulation does not require access to SUNSI (+25 Answers to petition for intervention; +7 petitioner/requestor reply).
20	U.S. Nuclear Regulatory Commission (NRC) staff informs the requester of the staff's determination whether the request for access provides a reasonable basis to believe standing can be established and shows need for SUNSI. (NRC staff also informs any party to the proceeding whose interest independent of the proceeding would be harmed by the release of the information.) If NRC staff makes the finding of need for SUNSI and likelihood of standing, NRC staff begins document processing (preparation of redactions or review of redacted documents).
25	If NRC staff finds no "need" or no likelihood of standing, the deadline for petitioner/requester to file a motion seeking a ruling to reverse the NRC staff's denial of access; NRC staff files copy of access determination with the presiding officer (or Chief Administrative Judge or other designated officer, as appropriate). If NRC staff finds "need" for SUNSI, the deadline for any party to the proceeding whose interest independent of the proceeding would be harmed by the release of the information to file a motion seeking a ruling to reverse the NRC staff's grant of access.
30	Deadline for NRC staff reply to motions to reverse NRC staff determination(s).
40	(Receipt +30) If NRC staff finds standing and need for SUNSI, deadline for NRC staff to complete information processing and file motion for Protective Order and draft Non-Disclosure Affidavit. Deadline for applicant/licensee to file Non-Disclosure Agreement for SUNSI.
A	If access granted: Issuance of presiding officer or other designated officer decision on motion for protective order for access to sensitive information (including schedule for providing access and submission of contentions) or decision reversing a final adverse determination by the NRC staff.
A + 3	Deadline for filing executed Non-Disclosure Affidavits. Access provided to SUNSI consistent with decision issuing the protective order.
A + 28	Deadline for submission of contentions whose development depends upon access to SUNSI. However, if more than 25 days remain between the petitioner's receipt of (or access to) the information and the deadline for filing all other contentions (as established in the notice of hearing or opportunity for hearing), the petitioner may file its SUNSI contentions by that later deadline.
A + 53	(Contention receipt +25) Answers to contentions whose development depends upon access to SUNSI.
A + 60	(Answer receipt +7) Petitioner/Intervenor reply to answers.
>A + 60	Decision on contention admission.

[FR Doc. 2016–16762 Filed 7–14–16; 8:45 am]

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[3] Requesters should note that the filing requirements of the NRC's E-Filing Rule (72 FR 49139; August 28, 2007) apply to appeals of NRC staff determinations (because they must be served on a presiding officer or the Commission, as applicable), but not to the initial SUNSI request submitted to the NRC staff under these procedures.

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–389; NRC–2015–0235]

Florida Power & Light Company; St. Lucie Plant, Unit No. 2

AGENCY: Nuclear Regulatory Commission.

ACTION: Director's decision under 10 CFR 2.206; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC or the Commission) has issued a director's decision with regard to a petition dated March 10, 2014, as supplemented, filed by the Southern Alliance for Clean Energy (SACE, the petitioner), requesting that the NRC take action with regard to St. Lucie Plant, Unit No. 2 (SL–2). The petitioner's requests and the director's decision are included in the **SUPPLEMENTARY INFORMATION** section of this document.

ADDRESSES: Please refer to Docket ID NRC–2015–0235 when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document using any of the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2015–0235. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.*
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select "*ADAMS Public Documents*" and then select "*Begin Web-based ADAMS Search.*" For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that a document is referenced.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

SUPPLEMENTARY INFORMATION: Notice is hereby given that the Director, Office of Nuclear Reactor Regulation, has issued director's decision DD–16–02 (ADAMS Accession No. ML16167A086) on a petition filed by the petitioner on March 10, 2014 (ADAMS Accession No. ML14071A431), as supplemented.[1]

The petitioner requested a hearing on what the petitioner characterized as a *de facto* license amendment for the replacement of the steam generators (SGs) in 2007 at SL–2, under § 50.59 of title 10 of the *Code of Federal Regulations* (10 CFR), "Changes, tests and experiments." SACE requested that the NRC revoke the *de facto* license amendment and stay the restart of SL–2 from the March 3, 2014, refueling outage pending resolution of the hearing request. As the basis for this request, the petitioner stated that Florida Power & Light Company (the licensee) misapplied 10 CFR 50.59 and that the SG replacement should have required a license amendment. The petitioner also expressed concerns (1) related to the inspection of the replacement SGs and (2) regarding the effects of the extended power uprate (EPU) on SG tube inservice inspection and flow-induced effects on the SG internals.

The Commission, by a memorandum and order (CLI–14–04) dated April 1, 2014 (ADAMS Accession No. ML14091B118), denied SACE's request to stay the restart of SL–2 from the March 3, 2014, refueling outage. Subsequently, by a memorandum and order (CLI–14–11) dated December 19, 2014 (ADAMS Accession No. ML14353A114), the Commission denied SACE's hearing request, concluded that the NRC did not issue the licensee a *de facto* license amendment, and referred SACE's safety concerns regarding the replacement SGs at SL–2 to the NRC's Executive Director for Operations for disposition under 10 CFR 2.206, "Requests for action under this subpart." Therefore, the staff treated these concerns in SACE's hearing request as a petition for enforcement action pursuant to 10 CFR 2.206. On February 24, 2015, (ADAMS Accession No. ML15057A221) and August 5, 2015 (ADAMS Accession No. ML15217A443), SACE informed the NRC staff by telephone that it had decided not to request a meeting with the NRC's Petition Review Board with regard to its 10 CFR 2.206 petition.

By letter dated September 28, 2015 (ADAMS Accession No. ML15205A313), the NRC acknowledged receipt of SACE's 10 CFR 2.206 petition and notified SACE of the NRC's acceptance of a portion of the petition (*i.e.,* one of SACE's safety concerns) for review in the 10 CFR 2.206 process. The portion of the petition that the NRC accepted for review under the 10 CFR 2.206 process addresses the licensee's application of 10 CFR 50.59 with respect to the change in a methodology for evaluating SGs, as described in the updated final safety analysis report (UFSAR). The letter also stated that the NRC staff was evaluating whether the licensee properly applied 10 CFR 50.59 when it changed the structural analysis codes as described in the UFSAR.

The staff's September 28, 2015, letter explained why the NRC did not accept the remaining portion of the petition for review under the 10 CFR 2.206 process. This portion of the petition raised safety concerns related to (1) inspection of the replacement SGs and (2) the effects of the EPU on SG tube inservice inspection and flow-induced effects on the SG internals. These concerns met the criteria for rejection in NRC Management Directive 8.11, "Review Process for 10 CFR 2.206 Petitions," dated October 25, 2000 (ADAMS Accession No. ML041770328), because the concerns had already been reviewed, evaluated, and resolved by the NRC staff.

By letters to the petitioner and licensee dated May 24, 2016 (ADAMS Accession Nos. ML16055A311 and ML16055A330, respectively), the NRC issued the proposed director's decision (ADAMS Accession No. ML16055A284) for comment. The petitioner and the licensee were asked to provide comments within 15 days on any part of the proposed director's decision that was considered to be erroneous or any issues in the petition that were not addressed. The NRC staff did not receive any comments on the proposed director's decision.

The Director of the Office of Nuclear Reactor Regulation has denied the petitioner's requested enforcement actions against the licensee. The reasons for this decision are explained in director's decision DD–16–02 pursuant to 10 CFR 2.206 of the Commission's regulations.

The NRC will file a copy of the director's decision with the Secretary of the Commission for the Commission's review in accordance with 10 CFR 2.206. As provided by this regulation, the director's decision will constitute the final action of the Commission 25 days after the date of the decision unless the Commission, on its own motion, institutes a review of the director's decision in that time.

Rockville, Maryland, this 8th day of July 2016.

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[1] Supplements (ADAMS Accession Nos. ML14115A457, ML14115A458, ML14125A514, ML14128A557, ML14143A412, ML14147A523, ML14310A811, and ML14337A792).

For the Nuclear Regulatory Commission.

William M. Dean,

Director, Office of Nuclear Reactor Regulation.

[FR Doc. 2016–16763 Filed 7–14–16; 8:45 am]

BILLING CODE 7590–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78276; File No. SR–CBOE–2016–041]

Self-Regulatory Organizations; Chicago Board Options Exchange, Incorporated; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Fees Schedule

July 11, 2016.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the "Act"),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on June 28, 2016, Chicago Board Options Exchange, Incorporated (the "Exchange" or "CBOE") filed with the Securities and Exchange Commission (the "Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of the Substance of the Proposed Rule Change

The Exchange proposes to amend its Fees Schedule. The text of the proposed rule change is available on the Exchange's Web site (*http://www.cboe.com/AboutCBOE/CBOELegalRegulatoryHome.aspx*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its Fees Schedule, effective July 1, 2016. Specifically, the Exchange proposes to adopt a program that offers a monthly subsidy to Trading Permit Holders ("TPHs") with executing agent operations[3] during the Extended Trading Hours ("ETH") trading session.

To participate in the ETH Executing Agent Subsidy Program, a TPH must be a designated ETH executing agent. To become a designated ETH executing agent, a TPH must submit a form to the Exchange.[4] The TPH must include on or with the form information demonstrating it maintains an ETH executing agent operation: (1) Physically staffed throughout each entire ETH trading session[5] and (2) willing to accept and execute orders on behalf of customers, including customers for which the agent does not hold accounts. The designation will be effective the first business day of the following calendar month, subject to the Exchange's confirmation the TPH's ETH executing agent operations satisfies [sic] these two conditions, and will remain in effect until the Exchange receives an email from the TPH terminating its designation or the Exchange determines the TPH's ETH executing agent operation no longer satisfies these two conditions.

A designated ETH executing agent will be eligible to receive a $5,000 monthly subsidy if it executes at least 1,000 contracts on behalf of customers (including public and broker-dealer customers) during ETH in a calendar month (which is an average of 50 contracts per ETH trading session, assuming a 20-trading day month). Within two business days following the end of a calendar month, in order to receive the subsidy for that month, the designated ETH executing agent must submit to the Exchange (in a form and manner determined by the Exchange) documentation and other evidence it executed at least 1,000 contracts on behalf of customers during ETH that month.

The Exchange believes this program will incentivize TPHs to conduct executing agent operations during ETH to increase customer accessibility to the ETH trading session. The purpose of the subsidy is to help TPHs offset the costs that accompany this type of operation during ETH, including costs related to staffing and clearing.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Act and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[6] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[7] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[8] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers. The Exchange also believes the proposed rule change is consistent with Section 6(b)(4) of the Act,[9] which requires that Exchange rules provide for the equitable allocation of reasonable dues, fees, and other charges among its Trading Permit Holders and other persons using its facilities.

In particular, the ETH Executing Agent Subsidy Program is reasonable because it incentivizes TPHs to conduct executing agent operations willing to accept orders from all customers during ETH to increase customer accessibility to the ETH trading session, which removes impediments to and perfects the mechanism of a free and open market and a national market system. By encouraging TPHs to conduct this type of operation during ETH, this program may result in additional order flow and liquidity during ETH, which creates greater trading opportunities and benefits all market participants trading during ETH.

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[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] An executing agent operation is one that accepts orders from customers (who may be public or broker-dealer customers, and including customers for which the agent does not hold accounts) and submits the orders for execution (either directly to the Exchange or through another TPH).

[4] The ETH Executing Agent Subsidy Registration Form may be submitted to *Registration@cboe.com*. A TPH must submit the form to the Exchange no later than 3:00 p.m. on the second to last business day of a calendar month to be designated an ETH executing agent under the program, and thus eligible for the subsidy, beginning the following calendar month.

[5] This generally means the TPH has persons available during all hours of the ETH trading session to take orders (such as by telephone) from customers.

[6] 15 U.S.C. 78f(b).

[7] 15 U.S.C. 78f(b)(5).

[8] *Id.*

[9] 15 U.S.C. 78f(b)(4).

The Exchange believes limiting the program to TPHs conducting executing agent operations willing to accept orders from all customers is equitable and not unfairly discriminatory due to the additional risks and potential costs (including those related to staffing and clearing) associated with this type of business, as well as the benefits this type of operation may provide during ETH (including increased customer accessibility to the ETH trading session). All TPHs that conduct this type of operation during ETH have an opportunity to become a designated ETH executing agent and thus eligible for the monthly subsidy.

The Exchange believes the amount of the subsidy is reasonable based on its understanding of the additional costs and risks associated with the executing agent operation during ETH. Additionally, the Exchange believes the 1,000 contract volume threshold is reasonable based on current ETH volumes.

B. Self-Regulatory Organization's Statement on Burden on Competition

CBOE does not believe the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. All TPHs that conduct executing agent operations willing to accept orders from all customers have an opportunity to be eligible for the program, and thus the monthly subsidy. The Exchange believes limiting the program to TPHs conducting this type of operation is equitable and not unfairly discriminatory due to the additional risks and potential costs (including those related to staffing and clearing) associated with this type of business, as well as the benefits this type of operation may provide during ETH (including increased customer accessibility to the ETH trading session). All designated ETH executing agents must meet the same volume threshold to qualify for the same monthly subsidy. The subsidy is designed to provide opportunities for more customers to submit orders during ETH, which generates more order flow and liquidity during that trading session and benefits all market participants.

As CBOE is the only Exchange currently offering an ETH session, the Exchange does not believe the proposed rule change will impose any burden on intermarket competition not necessary or appropriate in furtherance of the purposes of the Act. The Exchange notes, should this program make CBOE more attractive for trading, market participants can always elect to become TPHs and take part in this program, and take advantage of potential increased trading volume and opportunities during ETH that may result from the program.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act[10] and paragraph (f) of Rule 19b–4[11] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–CBOE–2016–041 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–CBOE–2016–041. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street, NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–CBOE–2016–041, and should be submitted on or before August 5, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[12]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–16717 Filed 7–14–16; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78278; File No. SR–BX–2016–041]

Self-Regulatory Organizations; NASDAQ BX, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Fees Under Rule 7018

July 11, 2016.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on June 30, 2016, NASDAQ BX, Inc. ("BX" or "Exchange") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items I, II, and III, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

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[10] 15 U.S.C. 78s(b)(3)(A).

[11] 17 CFR 240.19b–4(f).

[12] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the Exchange's transaction fees at Rule 7018 to: (i) Eliminate a $0.0017 per share executed credit tier that is provided for an order that accesses liquidity; and (ii) eliminate a $0.0019 per share executed fee tier charged for providing liquidity to the System.

While these amendments are effective upon filing, the Exchange has designated the proposed amendments to be operative on July 1, 2016.

The text of the proposed rule change is available on the Exchange's Web site at *http://nasdaqbx.cchwallstreet.com/*, at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to: (i) Eliminate a credit tier provided for an order that accesses liquidity; and (ii) eliminate a fee tier charged for providing liquidity to the System.

First Change

The purpose of the first proposed change is to eliminate a $0.0017 per share executed credit tier provided for an order that accesses liquidity. The Exchange currently provides a $0.0017 per share executed credit for an order that accesses liquidity (excluding orders with Midpoint pegging and excluding orders that receive price improvement and execute against an order with Midpoint pegging) entered by a member that accesses liquidity equal to or exceeding 0.20% of total Consolidated Volume[3] during a month. The Exchange also has two other credit tiers based on Consolidated Volume. Specifically, the Exchange provides a $0.0016 and a $0.0015 per share executed credit for an order that accesses liquidity (excluding orders with Midpoint pegging and excluding orders that receive price improvement and execute against an order with Midpoint pegging) entered by a member that accesses liquidity equal to or exceeding 0.10% or 0.05% of total Consolidated Volume during a month, respectively. All other orders that remove liquidity (excluding orders with Midpoint pegging and excluding orders that receive price improvement and execute against an order with Midpoint pegging) receive a credit of $0.0006 per share executed. The Exchange has observed that very few members qualify for the $0.0017 per share executed credit tier and it has not been effective at providing incentive to market participants to achieve the level of Consolidated Volume needed to qualify for the credit. Accordingly, the Exchange is proposing to eliminate the $0.0017 per share executed credit tier.

Second Change

The purpose of the second proposed change is to eliminate a $0.0019 per share executed fee tier charged for providing liquidity to the System. The Exchange currently assesses a fee of $0.0019 per share executed for a displayed order entered by a member that adds liquidity equal to or exceeding 0.10% of total Consolidated Volume during a month. The Exchange also has two other fee tiers based on Consolidated Volume. Specifically, the Exchange assesses a $0.0017 per share executed and $0.0014 per share executed charge for a displayed order entered by a member that adds liquidity equal to or exceeding 0.15% or 0.25% of total Consolidated Volume during a month, respectively. All other displayed orders that provide liquidity are assessed a fee of $0.0020 per share executed. The Exchange has observed that few members qualify for the $0.0019 per share executed fee. Thus, the $0.0019 per share executed fee tier has been ineffective at providing incentive to members to provide the level of Consolidated Volume needed to qualify for the reduced fee and the Exchange believes that removing the tier from the fee schedule is appropriate.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act[4] in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act[5] in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

First Change

The Exchange believes that eliminating the $0.0017 per share executed credit tier provided for an order that accesses liquidity is reasonable because it is not providing adequate incentive to market participants to remove liquidity from the Exchange. The Exchange must, from time to time, assess the effectiveness of the criteria it applies in providing reduced charges and credits, including the nature of the market improving behavior required to receive the reduced charge or credit. The Exchange will modify or eliminate such criteria when it believes the criteria are ineffective, which in turn may allow the Exchange to offer other incentives instead. The Exchange may also adjust the level or reduced charge or credit based on its observations of market participant behavior. In this instance, the Exchange believes that both the criteria for the $0.0017 per share executed credit and the level of the credit itself were ineffective at providing meaningful incentive to market participants to improve the market appreciably. The Exchange is limited in terms of the levels of reduced fees and credits that it can offer, and has consequently determined that it should eliminate the credit tier at this juncture. The Exchange notes that it is continuing to provide other opportunities for members to receive credits, including credit tiers that are based on Consolidated Volume. Eliminating the credit tier will apply to all market participants equally, and will impact only a small number of members that, in any given month, qualify for the credit. Such members will continue to have opportunity to qualify for the lower Consolidated Volume-based credit tiers. Thus, the Exchange believes that the proposed elimination of the $0.0017 per share executed credit tier is an equitable allocation and is not unfairly discriminatory.

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[3] Consolidated Volume is defined as the total consolidated volume reported to all consolidated transaction reporting plans by all exchanges and trade reporting facilities during a month in equity securities, excluding executed orders with a size of less than one round lot. For purposes of calculating Consolidated Volume and the extent of a member's trading activity the date of the annual reconstitution of the Russell Investments Indexes shall be excluded from both total Consolidated Volume and the member's trading activity. As used in this rule, "price improvement" shall mean instances when the accepted price of an order differs from the executed price of an order. *See* Rule 7018.

[4] 15 U.S.C. 78f(b).

[5] 15 U.S.C. 78f(b)(4) and (5).

Second Change

The Exchange believes that elimination of the $0.0019 per share executed fee tier charged for providing liquidity to the System is reasonable because it is not providing adequate incentive to market participants to remove liquidity from the Exchange. As discussed above, the Exchange must, from time to time, assess the effectiveness of the criteria it applies in providing reduced charges and credits, including the nature of the market improving behavior required to receive the reduced charge or credit. The Exchange has observed that very few members qualify for the $0.0019 per share executed fee, with more members qualifying for the lower fee tiers. The Exchange believes that both the criteria for the $0.0019 per share executed fee and the level of the reduced fee itself were ineffective at providing meaningful incentive to market participants to improve the market appreciably. As a consequence, the Exchange has determined to eliminate the fee tier at this juncture. The Exchange notes that it is continuing to provide other opportunities for members to receive reduced fees, including reduced fee tiers that are based on Consolidated Volume. Eliminating the fee tier will apply to all market participants equally, and will impact only a small number of members that in any given month qualify for the reduced fee. All members, including the small number that currently would qualify for the eliminated fee tier, will continue to have opportunity to qualify for the lower Consolidated Volume-based fee tiers. Thus, the Exchange believes that elimination of the $0.0019 per share executed fee tier is an equitable allocation and is not unfairly discriminatory.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. In terms of inter-market competition, the Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues if they deem fee levels at a particular venue to be excessive, or rebate opportunities available at other venues to be more favorable. In such an environment, the Exchange must continually adjust its fees to remain competitive with other exchanges and with alternative trading systems that have been exempted from compliance with the statutory standards applicable to exchanges. Because competitors are free to modify their own fees in response, and because market participants may readily adjust their order routing practices, the Exchange believes that the degree to which fee changes in this market may impose any burden on competition is extremely limited.

In this instance, the proposed changes to the charges assessed and credits available to member firms for execution of securities in securities of all three Tapes do not impose a burden on competition because the Exchange's execution services are completely voluntary and subject to extensive competition both from other exchanges and from off-exchange venues. The proposed changes to the charges assessed and credits provided to members for execution of orders do not impose a burden on competition because the Exchange's execution services are completely voluntary and subject to extensive competition both from other exchanges and from off-exchange venues. The proposed changes are reflective of this competition and the Exchange's desire to offer lower fees and credits in return for market-improving liquidity, which is ultimately limited by the Exchange's need to cover costs and make a profit. Thus, the Exchange must carefully adjust its fees and credits with the understanding that if the proposed changes are unattractive to market participants, it is likely that the Exchange will lose market share to other exchanges and off-exchange venues as a result. In this proposal, the Exchange is eliminating a credit tier and a fee tier, neither of which have proved effective at providing market participants with incentive to provide the market-improving behavior required to qualify for the two tiers. Accordingly, the Exchange is eliminating the tiers, and may offer other tiers in the future better designed to provide incentive to market participants to improve the market. The Exchange believes that the changes are pro-competitive, since any other market is free to provide similar, if not better, incentives fees and credits should they choose to do so, which may attract market participants to those markets to the detriment of the Exchange. For these reasons, the Exchange does not believe that the proposed changes will impair the ability of members or competing order execution venues to maintain their competitive standing in the financial markets.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.[6]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) Necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–BX–2016–041 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–BX–2016–041. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–BX–2016–041 and should be submitted on or before August 5, 2016.

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[6] 15 U.S.C. 78s(b)(3)(A)(ii).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[7]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–16719 Filed 7–14–16; 8:45 am]

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[7] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78280; File No. SR–NYSEArca–2016–91]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Amending NYSE Arca Rule 3.3 To Delete an Outdated Reference

July 11, 2016.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (the "Act" or "Exchange Act")[2] and Rule 19b–4 thereunder,[3] notice is hereby given that on June 28, 2016, NYSE Arca, Inc. (the "Exchange" or "NYSE Arca") filed with the Securities and Exchange Commission (the "Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Exchange has designated this proposal as a "non-controversial" proposed rule change pursuant to Section 19(b)(3)(A) of the Act[4] and Rule 19b–4(f)(6)(iii) thereunder,[5] which renders it effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of the Substance of the Proposed Rule Change

The Exchange proposes to amend NYSE Arca Rule 3.3 (Board Committees) to delete an outdated reference. The proposed rule change is available on the Exchange's Web site at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend NYSE Arca Rule 3.3(a)(1)(B) to delete an outdated reference to "a director of NYSE Regulation, Inc. that satisfies the Public Director requirements set forth in Section 3.02(a) of the Bylaws of the Exchange."

In 2015, the Exchange amended, among other rules, Rule 3.3 in order to establish a Regulatory Oversight Committee ("ROC") as a committee of the SRO Board.[6] At the time, the Exchange's regulatory functions were performed by NYSE Regulation, Inc. ("NYSE Regulation"), a former subsidiary of the Exchange's affiliate New York Stock Exchange LLC ("NYSE"), pursuant to an intercompany Regulatory Service Agreement ("RSA").[7] When the Exchange's ROC was created, Rule 3.3(a)(1)(B) was amended to provide that the ROC would consist of at least three members, each of whom would be a director of either the Exchange or of NYSE Regulation and who satisfied the independence requirements of the Exchange.[8]

The intercompany RSA terminated on February 16, 2016. As of that date, NYSE Regulation ceased to provide regulatory services to the Exchange, which re-integrated its regulatory functions. NYSE Regulation has also since been merged out of existence. The reference to a director of NYSE Regulation in Rule 3.3 is thus obsolete. The ROC currently consists of Exchange directors that satisfy the Exchange's independence requirements.[9] To effectuate the proposed change, the Exchange would delete the phrase "or a director of NYSE Regulation, Inc. that satisfies the Public Director requirements set forth in Section 3.02(a) of the Bylaws of the Exchange" in Rule 3.3(a)(1)(B).

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Exchange Act[10] in general, and with Section 6(b)(5)[11] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, and to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, help to protect investors and the public interest. Specifically, the Exchange believes that replacing the reference to a director of NYSE

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[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] 15 U.S.C. 78s(b)(3)(A).

[5] 17 CFR 240.19b–4(f)(6)(iii).

[6] *See* Securities Exchange Act Release No. 75155 (June 11, 2015), 80 FR 34744 (June 17, 2015) (SR–NYSEArca–2015–29) ("NYSE Arca ROC Approval Order").

[7] *See id.,* at 34744 & n.7; *see also* Securities Exchange Act Release No. 75991 (September 28, 2015), 80 FR 59837 (October 2, 2015) (SR–NYSE–2015–27).

[8] *See* NYSE Arca ROC Approval Order, 80 FR at 34744. Article III, Section 3.02(a) of the Exchange's Bylaws requires that at least 50% of the Exchange's directors be public directors, defined as "persons from the public and [who] will not be, or be affiliated with, a broker-dealer in securities or employed by, or involved in any material business relationship with, the Exchange or its affiliates." The Exchange believes that the Bylaw requirements for "public directors" establish the Exchange's criteria for director independence, and therefore serve the same purpose as the NYSE and NYSE MKT Independence Policies. *See* Securities Exchange Act Release Nos. 74824 (April 28, 2015), 80 FR 25347, 25348 n.6 (May 4, 2015) (SR–NYSEArca–2015–29) ("Notice"); NYSE Arca ROC Approval Order, 80 FR at 34744. *See also* Securities Exchange Act Release No. 67564 (August 1, 2012), 77 FR 47161 (August 7, 2012) (SR–NYSE–2012–17); SR–NYSEArca–2012–59; SR–NYSEMKT–2012–07) (approving NYSE's and NYSE MKT's director independence policy).

[9] *See* note 8, *supra.*

[10] 15 U.S.C. 78f(b).

[11] 15 U.S.C. 78f(b)(5).

Regulation in Rule 3.3(a)(1)(B) removes impediments to and perfects the mechanism of a free and open market by removing confusion that may result from having obsolete references in the Exchange's rulebook. The Exchange further believes that the proposal removes impediments to and perfects the mechanism of a free and open market by ensuring that persons subject to the Exchange's jurisdiction, regulators, and the investing public can more easily navigate and understand the Exchange's rulebook. The Exchange believes that eliminating an obsolete reference would not be inconsistent with the public interest and the protection of investors because investors will not be harmed and in fact would benefit from increased transparency, thereby reducing potential confusion. Removing such obsolete references will also further the goal of transparency and add clarity to the Exchange's rules.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Exchange Act. The proposed rule change is not intended to address competitive issues but rather to delete obsolete references, thereby increasing transparency, reducing confusion, and making the Exchange's rules easier to understand and navigate.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6)(iii) thereunder.[12]

A proposed rule change filed under Rule 19b–4(f)(6)[13] normally does not become operative prior to 30 days after the date of the filing. However, Rule 19b–4(f)(6)(iii)[14] permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The Exchange states that the proposed rule change benefits persons subject to the Exchange's jurisdiction, regulators, and the investing public by making the Exchange's rulebook easier to navigate and understand by deleting an obsolete reference.[15]

The Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest. The proposal will reduce confusion and add clarity to the Exchange's rulebook by removing an outdated reference. Accordingly, the Commission hereby waives the 30-day operative delay and designates the proposed rule change as operative upon filing.[16]

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)[17] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–NYSEArca–2016–91 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEArca–2016–91. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEArca–2016–91, and should be submitted on or before August 5, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[18]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–16721 Filed 7–14–16; 8:45 am]

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[12] In addition, Rule 19b–4(f)(6)(iii) requires the Exchange to give the Commission written notice of the Exchange's intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[13] 17 CFR 240.19b–4(f)(6).

[14] 17 CFR 240.19b–4(f)(6)(iii).

[15] *See supra* Section II.A.2.

[16] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[17] 15 U.S.C. 78s(b)(2)(B).

[18] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meeting

Notice is hereby given, pursuant to the provisions of the Government in the Sunshine Act, Public Law 94–409, that the Securities and Exchange Commission Advisory Committee on Small and Emerging Companies will hold a public meeting on Tuesday, July 19, 2016, in Multi-Purpose Room LL–006 at the Commission's headquarters, 100 F Street NE., Washington, DC.

The meeting will begin at 9:30 a.m. (EDT) and will be open to the public. Seating will be on a first-come, first-served basis. Doors will open at 9:00 a.m. Visitors will be subject to security checks. The meeting will be webcast on the Commission's Web site at *www.sec.gov.*

On June 27, 2016, the Commission published notice of the Committee meeting (Release No. 33–10105), indicating that the meeting is open to the public and inviting the public to submit written comments to the Committee. This Sunshine Act notice is being issued because a majority of the Commission may attend the meeting.

The agenda for the meeting includes matters relating to rules and regulations affecting small and emerging companies under the federal securities laws.

For further information, please contact Brent J. Fields in the Office of the Secretary at (202) 551–5400.

Dated: July 12, 2016.

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–16867 Filed 7–13–16; 11:15 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78284; File No. SR–NYSEARCA–2016–49]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing of Amendment No. 1 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment No. 1, To Amend Rule 6.64 With Respect To Opening Trading in an Options Series

July 11, 2016.

I. Introduction

On March 23, 2016, NYSE Arca, Inc. ("Exchange") filed with the Securities and Exchange Commission ("Commission"), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")[1] and Rule 19b–4 thereunder,[2] a proposed rule change to amend Exchange Rule 6.64 regarding the process for opening trading in an options series. The proposed rule change was published for comment in the **Federal Register** on April 12, 2016.[3] The Commission received one comment letter on the proposed rule change.[4] On May 25, 2016, the Commission extended the time period within which to approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to disapprove the proposed rule change to July 11, 2016.[5] On July 8, 2016, the Exchange submitted Amendment No. 1 to the proposed rule change.[6] The Commission is publishing this notice to solicit comment on Amendment No. 1 to the proposed rule change from interested persons and is approving the proposed rule change, as modified by Amendment No. 1, on an accelerated basis.

II. Description of the Proposed Rule Change, as Modified by Amendment No. 1

Exchange Rule 6.64 sets forth the OX automated opening process.[7] Current Rule 6.64(b) provides that, after the primary market for the underlying security disseminates an opening trade or an opening quote, the Exchange will open the related option series automatically based on the following principles and procedures:

(A) The system will determine a single price at which a particular option series will be opened.

(B) Orders and quotes in the system will be matched up with one another based on price-time priority; provided, however, that Orders will have priority over Market Maker quotes at the same price.

(C) Orders in the OX Book that were not executed during the Auction Process, other than Opening Only orders, shall become eligible for the Core Trading Session immediately after the conclusion of the Auction Process.

(D) The OX System will not conduct an Auction Process if the bid-ask differential for that series is not within an acceptable range. For the purposes of this rule, an acceptable range shall mean within the bid-ask differential guidelines established pursuant to Rule 6.37(b)(1)(A)–(E).

(E) If the OX System does not open a series with an Auction Process, the OX System shall open the series for trading after receiving notification of an initial NBBO disseminated by OPRA for the series or on a Market Maker quote, provided that the bid-ask differential does not exceed the bid-ask differential specified under Rule 6.37A(b)(4).[8]

In addition, Rule 6.64(c) provides for how the OX System will determine the opening price of a series when an Auction Process is conducted.[9] Specifically, current Rule 6.64(c) states, in part, that the "opening price of a series will be the price, as determined by OX, at which the greatest number of contracts will trade at or nearest to the midpoint of the initial uncrossed NBBO disseminated by OPRA, if any, or the midpoint of the best quote bids and quote offers in the OX Book."[10]

The Exchange proposes several changes to Exchange Rule 6.64 and the OX opening process. The proposed changes would also affect the process of re-opening an options series after a trading halt.[11]

First, the Exchange proposes to amend Exchange Rule 6.64(b) so that trading in an options series will be opened automatically once the primary market for the underlying security disseminates both a quote and a trade that is at or within the quote.[12] Further, the Exchange proposes to specify that the opening process will occur at or after 9:30 a.m. Eastern Time.[13]

The Exchange also proposes to modify Exchange Rule 6.64(b)(E) so that if the OX System does not open a series with an Auction Process, trading in an options series could no longer open on a local Market Maker quote, but would instead require an initial uncrossed NBBO disseminated by OPRA.[14] According to the Exchange, OPRA disseminates an NBBO based on information collected from the exchanges.[15] Thus, the Exchange states, NYSE Arca's local Market Maker quotes would be disseminated back to the Exchange from OPRA and may or may not be at the same price as the NBBO.[16]

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[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 77539 (April 6, 2016), 81 FR 21639 ("Notice").

[4] *See* letter from Anonymous, dated May 3, 2016. The letter was generally supportive of the proposed rule change.

[5] *See* Securities Exchange Act Release No. 77912 (May 25, 2016), 81 FR 35105 (June 1, 2016).

[6] *See* Letter to Brent J. Fields, Secretary, Commission, from Martha Redding, Associate General Counsel, Assistant Secretary, NYSE Arca, LLC dated July 11, 2016. As more fully described below, in Amendment No. 1 the Exchange proposes additional modifications to Rule 6.64(c) to clarify and detail how the Exchange would determine the opening price upon dissemination of an NBBO from OPRA. Amendment No. 1 to the proposed rule change is also available on the Commission's Web site at: *https://www.sec.gov/comments/sr-nysearca-2016-49/nysearca201649.shtml.*

[7] *See* Exchange Rule 6.64. The term "OX" refers to the Exchange's electronic order delivery, execution and reporting system for designated option issues through which orders and quotes of Users are consolidated for execution and/or display. *See* Exchange Rule 6.1A(a)(13) (defining "OX").

[8] *See* Exchange Rule 6.64(b)(A)–(E).

[9] *See* Notice and current Exchange Rule 6.64(c).

[10] *See* current Exchange Rule 6.64(c).

[11] *See* Exchange Rule 6.64(d), which provides that the Exchange will follow the same procedures in opening after a trading halt as the procedures followed for the opening of the trading day.

[12] *See* proposed Rule 6.64(b).

[13] *See id.*

In addition, the Exchange proposes to amend Rule 6.64(c). As noted, current Rule 6.64(c) provides that if there is no initial uncrossed NBBO disseminated by OPRA, the System instead determines an opening price that is "at the midpoint of the best quotes and offers in the OX Book." The Exchange originally proposed to modify Rule 6.64(c) by eliminating this language so that the rule would no longer provide that the opening price of a series could be determined by reference to the best quote bids and offers in the System Book.[17] Thus, as originally proposed, the opening price of a series would be the price, as determined by the System, at which the greatest number of contracts will trade "at or nearest to the midpoint of the initial uncrossed NBBO disseminated by OPRA." [18] As more fully set forth in the Notice, the Exchange stated that the original proposed modification was a conforming change that was necessary because the Exchange would no longer open solely on a local Market Maker quote.[19]

In Amendment No. 1, the Exchange proposes further modifications to Rule 6.64(c) to clarify and detail how the Exchange would determine the opening price upon dissemination of an NBBO from OPRA. Under proposed Rule 6.64(c), as modified by Amendment No. 1, "[t]he opening price of a series will be the price, as determined by the System, at which the greatest number of contracts will trade at a price at or between the NBBO disseminated by OPRA." [20] In addition, in Amendment No. 1 the Exchange proposes to specify further the circumstances under which the System would use midpoint pricing.[21] In particular, proposed Rule 6.64(c), as modified by Amendment No. 1, would specify what would happen if there is a tie and the same number of contracts can trade at multiple prices. Specifically, proposed Rule 6.64(c), as modified by Amendment No. 1, would provide that if the same number of contracts can trade at multiple prices, the opening price is the price at which the greatest number of contracts can trade that is "at or nearest to the midpoint" of the NBBO disseminated by OPRA. The rule would further specify that (i) if one of such prices is equal to the price of any Limit Order(s) in the Consolidated Book, the opening price will be the same price as the Limit Order(s) with the greatest size and, if the same size, the highest price; and (ii) if there is a tie between price levels and no Limit Orders exist at either of the prices, the Exchange would use the higher price.[22] In connection with these proposed modifications, the Exchange further proposes to delete language in current Rule 6.64(c) referring to pricing by reference to the best quotes bids and offers in the System. According to the Exchange, the language proposed to be deleted is superfluous, as the Exchange would no longer use Market Maker quotes to determine the opening price.[23]

Finally, the Exchange proposes a new provision to permit the Exchange to deviate from the standard manner of the Auction Process, including adjusting the timing of the Auction Process in any option class, when the Exchange believes it to be necessary in the interest of a fair and orderly market.[24]

III. Discussion and Commission Findings

After careful review, the Commission finds that the proposed rule change, as modified by Amendment No. 1, is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.[25] In particular, the Commission finds that the proposed rule change, as modified by Amendment No. 1, is consistent with Section 6(b)(5) of the Act,[26] which requires, among other things, that the rules of a national securities exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. As noted above, the Commission received one comment letter regarding the proposal, expressing support.[27]

The Commission believes the Exchange's proposal to require both a disseminated quote and a trade within the quote in an underlying security before opening trading in the related options series, instead of either one or the other, is reasonably designed ensure that the underlying security has been opened pursuant to a robust price discovery process before the overlying option begins trading.[28]

The Exchange proposes that if it does not open a series with an Auction Process, it will open the series for trading after receiving notification of an initial uncrossed NBBO disseminated by OPRA.[29] The Exchange represents that opening an options series for trading after receiving an uncrossed NBBO from OPRA, rather than based on a local Market Maker quote, will eliminate ambiguity as to the source of the information for each options series and should lead to more accurate prices on the Exchange.[30]

Further, the Exchange proposes that if it does open a series with an Auction Process, the opening price of a series will be the price, as determined by the System, at which the greatest number of contracts will trade at a price at or between the NBBO disseminated by OPRA. The Exchange further proposes to specify how the System will determine an opening price if the same number of contracts can trade at multiple prices.[31] The Commission believes the proposed process for how the System will determine an opening price for an option series at or between the NBBO disseminated by OPRA, and the circumstances under which System would use midpoint pricing, should result in an opening price that is related to the current market for an option and is therefore reasonably designed to protect investors and the public interest.

In addition, the Commission believes it is appropriate to allow the Exchange the discretion to deviate from the standard manner of the Auction Process, as the proposal provides, when it believes it is necessary in the interests of a fair and orderly market. The Commission believes that the ability to exercise such discretion can be important in situations when, for example, the primary market for an options class is unable to open due to a systems or technical issue or if some other unanticipated circumstance arises. The Commission notes that it has previously approved provisions of this kind as consistent with the Act.[32]

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[14] *See* proposed Rule 6.64(b)(E).

[15] *See* Notice, *supra* note 3, at 21640.

[16] *See* Notice, *supra* note 3, at 21640.

[17] Specifically, the Exchange proposed to delete from current Rule 6.64(c) the words "if any, or the midpoint of the best quotes and offers in the OX Book."

[18] *See* Notice *supra* note 3 at 21640.

[19] *See id.*

[20] *See* Amendment No. 1 and proposed Rule 6.64(c).

[21] *See* Amendment No. 1 and proposed Rule 6.64(c).

[22] *See* Amendment No. 1 and proposed Rule 6.64(c).

[23] *See* Amendment No. 1 and proposed Rule 6.64(c).

[24] *See* proposed Rule 6.64(b)(F); *see also* Notice, *supra* note 3, at 21640. For a more detailed description of the original proposed rule change, *see* Notice, *supra* note 3.

[25] In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[26] 15 U.S.C. 78f(b)(5).

[27] *See supra* note 4.

[28] *See* Notice, *supra* note 3, at 21640.

[29] *See supra* note 14 and accompanying text.

[30] *See* Notice, *supra* note 3, at 21640.

[31] *See supra* note 21 and accompanying text.

The Commission further believes that the proposed rule change will provide transparency and enhance investors' understanding of the operation of the Exchange's opening process. For these reasons, the Commission believes that the proposed rule change, as modified by Amendment No. 1, is consistent with the Act.

IV. Solicitation of Comments on Amendment No. 1

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether Amendment No. 1 to the proposed rule change is consistent with the Exchange Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–NYSEARCA–2016–49 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEARCA–2016–49. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEARCA–2016–49 and should be submitted by August 5, 2016.

V. Accelerated Approval of Proposed Rule Change, as Modified by Amendment No. 1

The Commission finds good cause to approve the proposed rule change, as modified by Amendment No. 1, prior to the 30th day after the date of publication of notice of Amendment No. 1 in the **Federal Register**. As discussed above, Amendment No. 1 clarifies how the Exchange would determine the opening price upon dissemination of an NBBO from OPRA, an in particular specifies the circumstances in which "at or nearest to the midpoint" pricing is utilized during the Auction Process. Furthermore, the Commission believes it is appropriate to have these changes incorporated into the rules of the Exchange concurrently with the changes discussed in the original filing.

Accordingly, the Commission finds good cause, pursuant to Section 19(b)(2) of the Exchange Act,[33] to approve the proposed rule change, as modified by Amendment No. 1 on an accelerated basis.

VI. Conclusion

IT IS THEREFORE ORDERED, pursuant to Section 19(b)(2) of the Exchange Act,[34] that the proposed rule change (SR–NYSEArca–2016–49), as modified by Amendment No. 1 thereto, be, and it hereby is, approved on an accelerated basis.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[35]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–16715 Filed 7–14–16; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78281; File No. SR–FINRA–2016–025]

Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Relating to the Fee for the Regulatory Element of Continuing Education

July 11, 2016.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on July 1, 2016, Financial Industry Regulatory Authority, Inc. ("FINRA") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by FINRA. FINRA has designated the proposed rule change as "establishing or changing a due, fee or other charge" under Section 19(b)(3)(A)(ii) of the Act[3] and Rule 19b–4(f)(2) thereunder,[4] which renders the proposal effective upon receipt of this filing by the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of the Substance of the Proposed Rule Change

FINRA is proposing to amend Section 4 of Schedule A to the FINRA By-Laws to address the transition of the Regulatory Element of Continuing Education ("CE") to the FINRA CE Online System®.

The text of the proposed rule change is available on FINRA's Web site at *http://www.finra.org*, at the principal office of FINRA and at the Commission's Public Reference Room.

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[32] *See, e.g.*, Securities Exchange Act Release No. 71651 (March 5, 2014), 79 FR 13693 (March 11, 2014) (SR–BATS–2014–003).

[33] 15 U.S.C. 78s(b)(2).

[34] 15 U.S.C. 78s(b)(2).

[35] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(ii).

[4] 17 CFR 240.19b–4(f)(2).

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, FINRA included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. FINRA has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

As part of the transition to CE Online, FINRA is phasing out test center delivery of the CE Regulatory Element.[5] Specifically, effective July 1, 2016, the option to complete the Regulatory Element at a test center will no longer be available, and participants must complete their session using the CE Online System with the exception of participants who, pursuant to the Americans with Disabilities Act,[6] may need accommodations in completing their CE session due to a disability. Participants who need such accommodations may apply for an accommodation and complete their CE Regulatory Element session at a test center.[7]

Currently, pursuant to Section 4(f) of Schedule A to the FINRA By-Laws, FINRA assesses a session fee of $100 to each participant for each scheduled session to complete the Regulatory Element at a test center, and it assesses a session fee of $55 to each participant who completes the Regulatory Element through the CE Online System. In conjunction with phasing out test center delivery of the Regulatory Element, FINRA is proposing to amend Section 4(f) of Schedule A to the FINRA By-Laws to assess a session fee of $55 for the Regulatory Element regardless of whether the session is completed at a test center or through the CE Online System. However, as noted above, only participants who apply for an accommodation would be eligible to complete their CE Regulatory Element session at a test center.

In addition, Section 4(c) of Schedule A to the FINRA By-Laws includes additional fees for taking the Regulatory Element session outside the United States, failing to appear on time for an appointment or cancelling or rescheduling an appointment. FINRA is proposing to make technical changes to Sections 4(c)(3) and (4) of Schedule A to the FINRA By-Laws to clarify that such additional fees are only applicable to test center-based sessions. Further, because these additional fees are based on the initial session fee, which FINRA is proposing to reduce, the proposed rule change would result in a reduction of the total fees charged under these sections for completing the Regulatory Element at a test center.

FINRA has filed the proposed rule change for immediate effectiveness.

2. Statutory Basis

FINRA believes that the proposed rule change is consistent with the provisions of Section 15A(b)(5) of the Act,[8] which requires, among other things, that FINRA rules provide for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility or system that FINRA operates or controls. The proposed rule change reduces the session fee for participants who are eligible to complete their CE Regulatory Element session at a test center, and it aligns the session fee for such participants with the session fee for participants who complete their session through the CE Online System.

B. Self-Regulatory Organization's Statement on Burden on Competition

FINRA does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. As described above, participants who need an accommodation pursuant to the Americans with Disabilities Act may apply for an accommodation and complete their CE Regulatory Element session at a test center. FINRA is proposing to reduce the session fee for a test center-based session of the CE Regulatory Element for such participants.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act[9] and paragraph (f)(2) of Rule 19b–4 thereunder.[10] At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–FINRA–2016–025 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–FINRA–2016–025. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE.,

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[5] *See Regulatory Notice* 15–28 (August 2015); *see also Information Notice,* May 16, 2016 (Elimination of Continuing Education Delivery at Testing Centers).

[6] Americans with Disabilities Act of 1990, Public Law 101–336, 104 Stat. 328 (1990).

[7] *See* FINRA's CE Online Delivery Accommodation Web page, available at *http://www.finra.org/industry/accommodations-continuing-education-ce-online-participants.*

[8] 15 U.S.C. 78*o*–3(b)(5).

[9] 15 U.S.C. 78s(b)(3)(A).

[10] 17 CFR 240.19b–4(f)(2).

Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of FINRA. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–FINRA–2016–025, and should be submitted on or before August 5, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[11]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–16722 Filed 7–14–16; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78286; File No. SR–BX–2016–032]

Self-Regulatory Organizations; NASDAQ BX, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to the Automated Removal of Quotes

July 11, 2016.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on July 1, 2016, NASDAQ BX, Inc. ("BX" or "Exchange") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Chapter VII, Section 6(f), entitled "Automated Removal of Quotes."

The text of the proposed rule change is available on the Exchange's Web site at *http://nasdaqomxbx.cchwallstreet.com/*, at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend BX Rules at Chapter VII, Section 6(f), entitled "Automated Removal of Quotes" to modify the minimum Specified Percentage (as described below). A BX Options Market Maker[3] sets the Specified Percentage to enhance its risk management for an underlying security as market conditions warrant, based on its own risk tolerance level and quoting behavior. The Exchange proposes to permit the BX Options Market Maker to set the Specified Percentage more broadly, no less than 1%, with this rule change. The Exchange also proposes to replace the definition of "disseminated size"[4] with a quantitative description to add transparency with respect to the calculation of Series Percentage.

Background

Today, Chapter VII, Section 6(f) permits BX Options Market Makers to monitor risk arising from multiple executions across multiple options series of a single underlying security. A BX Options Market Maker may provide a specified time period and a specified percentage by which the Exchange's System will automatically remove a BX Options Market Maker's quotes in all series of an underlying security submitted through designated BX protocols, as specified by the Exchange, during a specified time period not to exceed 15 seconds ("Percentage-Based Specified Time Period").[5]

For each series in an option, the System determines: (i) The percentage that the number of contracts executed in that series represents relative to the BX Options Market Maker's disseminated size of each side in that series ("Series Percentage"); and (ii) the sum of the Series Percentage in the option issue ("Issue Percentage"). The Exchange proposes herein to replace the term "disseminated size" with the more precise phrase "number of contracts available at the time of execution plus the number of contracts executed in unexpired prior executions."

The System tracks and calculates the net impact of positions in the same option issue during the Percentage-Based Specified Time Period. Specifically, the System tracks transactions, *i.e.*, the sum of buy-side put percentages, the sum of sell-side put percentages, the sum of buy-side call percentages, and the sum of sell-side call percentages. The System then calculates the absolute value of the difference between the buy-side puts and the sell-side puts plus the absolute value of the difference between the buy-side calls and the sell-side calls. If the Issue Percentage, rounded to the nearest integer, equals or exceeds a percentage established by the BX Options Market Maker, not less than 100% ("Specified Percentage"), the System automatically removes a BX Options Market Maker's quotes in all series of an underlying security submitted through designated BX protocols, as specified by the Exchange, during the Percentage-Based Specified Time.

The Percentage-Based Specified Time Period commences for an option every time an execution occurs in any series in such option and continues until the System removes quotes as described in Chapter VII, Section 6(f)(iv) or (v) or the Percentage-Based Specified Time Period expires. The Percentage-Based Specified Time Period operates on a rolling basis among all series in an option in that there may be multiple Percentage-Based Specified Time Periods occurring simultaneously and such Percentage-Based Specified Time periods may overlap.

Proposal

The Exchange proposes to lower the minimum Specified Percentage, which is set by the BX Options Market Maker, from 100% to 1%. The proposal would amend the rule text to state, if the Issue Percentage, rounded to the nearest integer, equals or exceeds a percentage established by the BX Options Market Maker, not less than *1%* ("Specified Percentage"), the System automatically removes a BX Options Market Maker's quotes in all series of an underlying security submitted through designated BX protocols, as specified by the Exchange, during the Percentage-Based Specified Time. This proposal would allow a BX Options Market Maker to establish a Specified Percentage at any percentage level greater than or equal to 1% for an option in which the BX Options Market Maker is appointed. Today, the Specified Percentage would be set by the BX Options Market Maker at greater than or equal to 100%. This amendment will allow BX Options Market Makers to better manage their risk and assist them to avoid trading a number of contracts that exceeds the BX Options Marker Maker's risk tolerance level across multiple series of a single underlying when such series are executed in rapid succession.

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[11] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The term "BX Options Market Maker" or "Options Market Maker" (herein "BX Options Market Maker") means an Options Participant registered with the Exchange for the purpose of making markets in options contracts traded on the Exchange and that is vested with the rights and responsibilities specified in Chapter VII of these Rules." [sic] *See* BX Rules at Chapter I, Section 1(a)(9).

[4] *See* Securities Exchange Act Release No. 76317 (October 30, 2015), 80 FR 68586 at 68587 (November 5, 2015) (SR–BX–2015–060). The Exchange defined disseminated size in this rule change in footnote 12, as the original size quoted by the Participant.

[5] A specified time period commences for an option when a transaction occurs in any series in such option.

BX Options Market Makers will be able to more precisely customize their risk settings within the System. BX Options Market Makers will be able to consider factors such as present and anticipated market conditions, news in an option, and a sudden change in volatility of an option. BX Options Market Makers are required to utilize either the Percentage Based Threshold or the Volume Based Threshold. BX Options Market Makers that select to utilize the Percentage-Based Threshold will be able to adopt more precise controls with this proposal based on the BX Options Market Maker's risk tolerance level. BX Options Market Makers must utilize either the Percentage-Based[6] or Volume-Based risk controls. BX Options Market Makers may contact Market Operations to set their percentage, which is 1% or greater with this proposal, and specified time period.

By way of example, if a BX Options Market Maker has set the percentage setting to 50% and a Specified Time Period of 15 seconds and the Order Book reflects:

MM1 has a displayed quote of 1.10 (100) × 1.20 (100) for IBM May 20, 2016 70 puts and MM1 is the only displayed size on BX and an order is submitted to buy 75 IBM May 20, 2016 70 Puts for 1.20.

Chapter VII, Section 6(f) would cause the following:

(1) Provide MM1 with an execution —Sld [sic] 75 @ 1.20; and

(2) Trigger the Percentage-Based Threshold and remove MM1's quotes in IBM.

Another example is with multiple executions. Presume the following:

MM1 has set the percentage setting to 80% by 5 seconds and MM1 has a displayed quote of 2.00 (100) × 2.25 (100) for IBM May 20, 2016 70 puts and he is the only displayed size on the BX. Also, presume an order comes in to buy 50 IBM May 20, 2016 70 puts for 2.25.

Chapter VII, Section 6(f) would cause the following:

(1) Provide MM1 with an execution—Sold 50 @ 2.25;

(2) Update MMI [sic] quote to 2.00 (100) × 2.25 (50);

(3) Within 1 second an order comes in to buy 45 IBM May 20, 2016 70 puts for 2.25;

(4) Provide MM1 with an execution—Sold 45 @ 2.25; and

(5) Trigger the Percentage-Based Threshold and remove MM1's quotes in IBM.

The Exchange also proposes to replace the term "disseminated size" with a quantitative description to add transparency with respect to the calculation of Series Percentage. The language proposed amends the original definition of disseminated size. With respect to the disseminated size, the Exchange previously defined disseminated size as ". . . the original size quoted by the Participant."[7]

The Exchange proposes to amend the definition as follows: "For each series in an option, the System will determine: (i) The percentage that the number of contracts executed in that series represents relative to the number of contracts available at the time of execution plus the number of contracts executed in unexpired prior executions of each side in that series ("Series Percentage"); and (ii) the sum of the Series Percentage in the option issue ("Issue Percentage")." The Exchange counts Specialized Quote Feed ("SQF")[8] quotes in determining the number of contracts traded and removed by the System. SQF permits a two-sided quote for each BX Options Market Maker.

By way of example, with the proposed definition, if a BX Options Market Maker with a Percentage-Based Specified Time Period of 10 seconds and a Specified Percentage of 100% submits a quote over SQF of 1.00 (100) × 1.10 (100) and a buy order executes 75, the remaining size would be 1.00 (100) × 1.10 (25). Thereafter a new Percentage-Based Specified Time Period begins and current Series Percentage executed is 75 and three seconds pass and the BX Options Market Maker re-quotes 1.00 (100) × 1.10 (100), an incoming buy order of 43 would cause the Issue Percentage to meet the Percentage-Based Threshold. This is due to a counted size of 175 (the executed 75 plus the newly quoted 100) and rounding (0.75 + 43/175 = 0.9957 rounds up to 100%). If the former definition applied, the size would have been 100 and an execution of only 25 contracts on the same side would have caused the Issue Percentage to meet the Percentage-Based Threshold, which is not the case. In other words, the current SQF quote on that side for that series (for that BX Options Market Maker) in addition to all the executions that have occurred on that side for that series (for that BX Options Market Maker) within the Percentage-Based Specified Time Period would comprise the size.

This new definition accurately represents the manner in which the Issue Percentage is calculated. Also, the more precise language within the rule text will provide BX Options Market Makers with a more accurate description of the operation of this risk mechanism. The Exchange has always calculated the BX Options Market Maker's size in this fashion. The definition, as described in the prior rule change, was not accurate and the Exchange seeks to amend the definition with this proposal and memorialize the definition within the rule.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act[9] in general, and furthers the objectives of Section 6(b)(5) of the Act[10] in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest, by offering BX Options Market Makers the ability to better manage their own risk with this risk feature.

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[6] BX Options Market Makers selecting the Percentage-Based risk control in Rule 1095(i) [sic] are required to provide a specified time period, up to 15 seconds, and a specified percentage with a number of 1% or greater, as proposed herein, to the BX Market Operations staff to select this risk control. If a BX Options Market Maker does not desire to utilize the Percentage-Based risk control the BX Options Market Maker must utilize the Volume-Based risk control which is similarly set-up by contacting Market Operations and providing certain settings.

[7] *See* note 4 above.

[8] SQF permits the receipt of quotes. SQF Auction Responses and market sweeps are also not included.

[9] 15 U.S.C. 78f(b).

[10] 15 U.S.C. 78f(b)(5).

BX Options Market Makers are obligated to submit continuous two-sided quotations in a certain number of series in their appointed option classes for a certain percentage of each trading session.[11] This obligation renders them vulnerable to risk from unusual market condition, volatility in specific options, and other market events that may cause them to receive multiple, extremely rapid automatic executions before they can adjust their quotations and overall risk exposure in the market. Without adequate risk management tools in place on the Exchange, the incentive for BX Options Market Makers to quote aggressively, respecting both price and size could be diminished. Such a result may undermine the quality of the markets, which are enhanced by the depth and liquidity such Market Makers provide in the marketplace.

By allowing the Specified Percentage provided by the BX Options Market Maker to be reduced from 100% to 1%, the Exchange provides its BX Options Market Makers the desired flexibility to take into account such factors as present and anticipated market conditions, news in an option or sudden change in volatility of an option without any limitation regarding the Specified Percentage. This should encourage BX Options Market Makers to provide additional depth and liquidity to the Exchange's markets, thereby removing impediments to and perfecting the mechanisms of a free and open market and a national market system and, in general, protecting investors and the public interest.

The proposal is consistent with the Act because the reduction of the Specified Percentage to not less than 1% provides more alternatives to BX Options Market Makers in setting their percentage without impacting their firm quote obligations. The System operates consistently with the firm quote obligations of a broker-dealer pursuant to Rule 602 of Regulation NMS. Specifically, with respect to BX Options Market Makers, their obligation to provide continuous two-sided quotes on a daily basis is not diminished by the removal of such quotes by the Percentage-Based Threshold. BX Options Market Makers are required to provide continuous two-sided quotes on a daily basis.[12] BX Options Market Makers that utilize the Percentage-Based Threshold will not be relieved of the obligation to provide continuous two-sided quotes on a daily basis, nor will the change prohibit the Exchange from taking disciplinary action against a BX Options Market Maker for failing to meet the continuous quoting obligation each trading day. All quotes entered into the System are considered firm. Quotes will only be removed from the System once the Percentage-Based Threshold has been met if the quote was not otherwise executed by an incoming order.

This risk feature will continue to remove impediments to and perfect the mechanism of a free and open market and a national market system and protect investors and the public interest by allowing BX Options Market Makers to remove their quotes in the event that market conditions warrant, based on their own risk tolerance level. BX Options Market Makers provide liquidity to the market place and have obligations unlike other market participants.[13] This risk feature is important because it will enable BX Options Market Makers to manage their exposure at the Exchange. Further, permitting BX Options Market Makers to enter a broader setting would continue to allow BX Options Market Makers to have flexibility in setting their risk exposure to prevent unintended triggers of the Percentage-Based Threshold. This proposal continues to allow BX Options Market Makers to also select a Percentage-Based Specified Time Period. Each BX Options Market Maker has different levels of sensitivity and its own system safeguards as well. The proposed setting would permit each BX Options Market Maker to select a setting that is appropriate to capture the needs of that BX Options Market Maker.

Further, it is important to note that any interest that is executable against a BX Options Market Maker's quotes and orders that are received[14] by the Exchange prior to the trigger of the Percentage-Based Threshold, which is processed by the System, automatically executes at a price up to the BX Options Market Maker's size. The system-generated Purge Notification Message is accepted by the System in the order of receipt in the queue and is processed in that order so that interest that is already accepted into the System is processed prior to the message. Incoming orders received prior to the Purge Notification Message would not be cancelled, rather they be [sic] executed at a price up to the BX Options Market Maker's size.

The Exchange notes that Miami International Securities Exchange, LLC ("MIAX") implemented a rule that changed its Allowable Engagement Percentage from a minimum of 100% to any percentage established by the Market Maker.[15] The BX rule is similar to MIAX's in that a member is required to have a setting, although MIAX has a default setting in place in the instance that no percentage is provided. BX Options Market Makers that select the Percentage-Based risk tool must provide the Exchange with a Percentage-Based Specified Time Period and a Specified Percentage greater than or equal to 1%.

Amending the definition of disseminated size will provide market participants with greater information on the manner in which the Exchange computes the Issue Percentage. The Exchange believes that the manner in which the Exchange calculates the number of contracts, which are counted for the Issue Percentage, is consistent with the Act. The counting method permits the Exchange to update the reference number to include the executed contracts. While this method differs from the method previously described, the Exchange believes that there is no industry standard for counting and its method permits market participants to achieve the desired risk protection. With the proposed definition, each execution uses the Percentage-Based Specified Time Period that existed at the time of the execution. BX Options Market Makers can change the Percentage-Based Specified Time Period at any time. If a BX Options Market Maker is using a Percentage-Based Specified Time Period of 15 seconds when an execution happens, then changes the Percentage-Based Specified Time Period to half a second, that first execution will not expire until 15 seconds have passed. The selected Percentage-Based Specified Time Period will persist for 15 seconds and the number of executed contracts will be included in the denominator of subsequent executions for a full 15 seconds.

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[11] Pursuant to BX Rules at Chapter VII, Section 5, entitled "Obligations of Market Makers", in registering as a market maker, an Options Participant commits himself to various obligations. Transactions of a BX Options Market Maker must constitute a course of dealings reasonably calculated to contribute to the maintenance of a fair and orderly market, and Market Makers should not make bids or offers or enter into transactions that are inconsistent with such course of dealings. Further, all Market Makers are designated as specialists on BX for all purposes under the Act or rules thereunder. *See* Chapter VII, Section 5.

[12] *Id.*

[13] *Id.*

[14] The time of receipt for an order or quote is the time such message is processed by the Exchange book.

[15] *See* Securities Exchange Act Release No. 77817 (May 12, 2016), 81 FR 31286 (May 18, 2016) (SR–MIAX–2016–10).

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The Percentage-Based Threshold is intended to protect BX Options Market Makers from exposure to excessive risk. The Exchange believes this proposal will foster competition by providing BX Options Market Makers with the ability to enhance and customize their percentage in order to compete for executions and order flow. Specifically, the proposal does not impose a burden on intra-market or inter-market competition; rather, it provides BX Options Market Makers with the opportunity to avail themselves of similar risk tools, which are currently available on other exchanges.[16] BX Options Market Makers quote across many series in an option creating the possibility of "rapid fire" executions that can create large, unintended principal positions that expose BX Options Market Makers. The Percentage-Based Threshold permits BX Options Market Makers to monitor risk arising from multiple executions across multiple options series of a single underlying security.

The Exchange is proposing this rule change to continue to permit BX Options Market Makers to reduce their risk in the event the BX Options Market Maker is suffering from a system issue or due to the occurrence of unusual or unexpected market activity. Reducing such risk will enable BX Options Market Makers to enter quotations without any fear of inadvertent exposure to excessive risk, which in turn will benefit investors through increased liquidity for the execution of their orders. Reducing risk by utilizing the proposed risk protections enables BX Options Market Makers, specifically, to enter quotations with larger size, which in turn will benefit investors through increased liquidity for the execution of their orders. Such increased liquidity benefits investors because they receive better prices and because it lowers volatility in the options market.

The Exchange believes that amending the definition of disseminated size does not create an undue burden on competition because the Exchange will uniformly calculate the Percentage-Based Threshold in a uniform manner for all BX Options Market Makers. The Exchange is memorializing the definition within the Rule.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act[17] and Rule 19b–4(f)(6) thereunder.[18] The Exchange has requested that the Commission waive the thirty-day operative delay so that the proposal may become operative immediately. The Commission believes that waiving the thirty-day operative delay is consistent with the protection of investors and the public interest. The Exchange proposes to change a setting in an existing risk protection feature to enhance market makers' ability to protect against excessive risk arising from multiple executions across multiple options series of a single underlying security. The Commission notes that another options exchange currently has a similar setting for a like risk protection feature for market makers. Moreover, the Commission notes that the proposal to replace the term "disseminated size" with an accurate and more precise description would add transparency with respect to the operation of the risk protection feature. Therefore, the Commission hereby waives the thirty-day operative delay and designates the proposal operative upon filing.[19]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–BX–2016–032 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–BX–2016–032. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–BX–2016–032 and should be submitted on or before August 5, 2016.

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[16] *See* Section 8 of the 19b4.

[17] 15 U.S.C. 78s(b)(3)(A).

[18] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and the text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[19] For purposes of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[20]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–16725 Filed 7–14–16; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78279; File No. SR–FINRA–2016–022]

Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Notice of Filing of a Proposed Rule Change To Amend Rule 12403 (Cases With Three Arbitrators) of the Code of Arbitration Procedure for Customer Disputes Relating to the Panel Selection Process in Arbitration

July 11, 2016.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on July 1, 2016, Financial Industry Regulatory Authority, Inc. ("FINRA") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by FINRA. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

FINRA is proposing to amend Rule 12403 of the Code of Arbitration Procedure for Customer Disputes ("Code") concerning customer cases with three arbitrators, to increase the number of public arbitrators on the list that FINRA sends parties during the arbitration panel selection process from 10 arbitrators to 15 arbitrators. FINRA would also increase the number of strikes that parties may make to the public list from four to six strikes to keep the proportion of strikes the same under the amended rule as it is under the current rule.

The text of the proposed rule change is available on FINRA's Web site at *http://www.finra.org,* at the principal office of FINRA and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, FINRA included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. FINRA has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Background

FINRA allows parties to participate in selecting the arbitrators who serve on their cases. Parties select their arbitration panel from computer generated lists of arbitrators that FINRA sends them. Under FINRA Rule 12403(a), in customer cases with three arbitrators,[3] FINRA sends the parties three lists: A list of 10 chair-qualified public arbitrators, a list of 10 public arbitrators, and a list of 10 non-public arbitrators.[4] The parties select their panel through a process of striking and ranking the arbitrators on the lists.[5] Under Rule 12403(c)(2), each party is allowed to strike up to four arbitrators on the chair-qualified public list and four arbitrators on the public list. At least six names must remain on each list. However, Rule 12403(c)(1) provides for unlimited strikes on the non-public list so that any party may select a panel of all public arbitrators in a customer case.

When parties collectively strike all of the non-public arbitrators from the list, FINRA fills all three panel seats from the two 10-person lists of public arbitrators. Specifically, the Code provides that when parties collectively strike all of the arbitrators appearing on the non-public list, FINRA returns to the public list to select the next highest ranked available arbitrator to fill the seat. If no public arbitrators remain available to fill the vacancy, FINRA returns to the chair-qualified public list to select the next highest ranked public chair. In doing so, there is a likelihood that FINRA will appoint an arbitrator who the parties accepted, but ranked lower on the public or chair-qualified public lists.

FINRA Dispute Resolution Task Force

In 2014, FINRA formed the FINRA Dispute Resolution Task Force ("Task Force") to suggest strategies to enhance the transparency, impartiality, and efficiency of FINRA's securities dispute resolution forum for all participants. The Task Force discussed panel selection in customer cases. During its discussions, the Task Force reviewed statistics on how often parties were striking all of the non-public arbitrators on the list. The data indicated that between September 30, 2013 (the effective date of the rule change providing for all public panels) and January 16, 2015, claimants struck all non-public arbitrators in 69 percent of cases. Given the data on strikes, the Task Force concluded that in many cases, the parties are selecting the three public arbitrators from the 20 candidates appearing on the public lists. The Task Force recommended that in instances where parties collectively strike all the non-public arbitrators, FINRA should provide a new list of 10 public arbitrators to fill the third public arbitrator seat.

Proposed Rule Change

FINRA agrees with the Task Force that FINRA should provide parties with greater choice of public arbitrators in cases with all public panels. However, if FINRA waits until the parties collectively strike all the non-public arbitrators from the list before it provides the parties with additional names of public arbitrators, the panel selection process is likely to take at least one additional month to complete. Also, FINRA is concerned about the additional time and expense the parties would incur in vetting an additional list of 10 public arbitrators.

To address the Task Force's recommendation without delaying the panel selection process, or unduly burdening the parties, FINRA is proposing to amend Rule 12403(a)(1) to increase the number of arbitrators on the public arbitrator list FINRA sends the parties from 10 to 15. In doing so, FINRA would provide greater choice of public arbitrators during the panel selection process, and minimize the burden of vetting additional public arbitrators later in the process.

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[20] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* FINRA Rule 12401 which provides that if the amount of a claim is more than $100,000, exclusive of interest and expenses, or is unspecified, or if the claim does not request money damages, the panel will consist of three arbitrators, unless the parties agree in writing to one arbitrator.

[4] Public arbitrators do not have an affiliation with the financial industry. The non-public arbitrator roster includes individuals who: (1) Are employed in the financial industry; (2) provide services to industry entities and their employees; or (3) devote a significant part of their business to representing or providing services to parties in disputes concerning investments or employment relationships.

[5] *See* FINRA Rule 12403(c) (Striking and Ranking Arbitrators).

FINRA is also proposing to amend Rule 12403(c)(2) to increase the number of strikes to the public arbitrator list from four to six, so that the proportion of strikes is the same under the amended rule as it is under the current rule. Task Force members felt strongly that parties wanted additional public arbitrators to choose from because they did not want FINRA to appoint lower ranked arbitrators to the panel. We are proposing to increase the number of strikes the parties can make to the newly increased public list to improve the likelihood that FINRA will appoint the parties' preferred arbitrators to the panel.

2. Statutory Basis

FINRA believes that the proposed rule change is consistent with the provisions of Section 15A(b)(6) of the Act,[6] which requires, among other things, that FINRA rules must be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, and, in general, to protect investors and the public interest. FINRA believes the proposed rule change would protect investors and the public interest by providing greater choice during the panel selection process for the parties in all customer cases with three arbitrators.

B. Self-Regulatory Organization's Statement on Burden on Competition

FINRA does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Current rules permit parties to an arbitration to strike a specified number of arbitrators from each list of arbitrators that FINRA sends them and require them to rank order the remaining arbitrators. The propensity to strike all non-public arbitrators combined with the current rules for selecting the panel has led to concerns that panels may include a party's least preferred arbitrator, thereby diminishing a party's overall satisfaction with the arbitration process at the forum.

To remedy this concern, FINRA proposes to expand the number of arbitrators on the public arbitrator list. The longer list will increase the parties' choice of arbitrators during the panel selection process, and will improve the likelihood that FINRA will appoint the parties' preferred arbitrators to the panel.

Forum users are likely to incur costs in vetting the five additional public arbitrators on the list FINRA would send them. However, forum practitioners have indicated that they would willingly incur the additional expense in order to have greater choice in selecting arbitrators.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve or disapprove such proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–FINRA–2016–022 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–FINRA–2016–022. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549–1090, on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filing also will be available for inspection and copying at the principal office of FINRA. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–FINRA–2016–022 and should be submitted on or before August 5, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[7]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–16720 Filed 7–14–16; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78277; File No. SR–OCC–2016–007]

Self-Regulatory Organizations; The Options Clearing Corporation; Order Approving Proposed Rule Change Related to The Options Clearing Corporation's Membership Approval Process

July 11, 2016.

On May 16, 2016, The Options Clearing Corporation ("OCC") filed with the Securities and Exchange Commission ("Commission") the proposed rule change SR–OCC–2016–007 pursuant to Section 19(b)(1) of the Securities and Exchange Act of 1934 ("Act")[1] and Rule 19b–4 thereunder.[2] The Commission did not receive any comments on the proposed rule change. This order approves the proposed rule change.

I. Description

OCC is changing its rules to: (i) Vest the authority to approve or disapprove new membership applications with OCC's Risk Committee,[3] and (ii) delegate authority to the Executive Chairman or President of OCC to approve new membership applications provided that: (a) It is not recommended that the Risk Committee impose additional membership criteria upon the applicant pursuant to Section 1, Interpretation and Policy .06 of Article V of OCC's By-Laws, and (b) the Risk Committee is given not less than five business days to determine that the application should be reviewed at a meeting of the Risk Committee and the Risk Committee has not requested that the application be reviewed at a meeting of the Risk Committee within such five day period.

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[6] 15 U.S.C. 78o–3(b)(6).

[7] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

This proposed rule change will streamline OCC's membership approval process by: (i) Allowing OCC's Executive Chairman or President to approve pro forma applications for clearing membership, and (ii) vesting ultimate authority with OCC's Risk Committee, not its Board, to approve or disapprove applications for clearing membership that are not approved by either OCC's Executive Chairman or President. The practical effect of the proposed rule change is that either OCC's Executive Chairman or President will approve most applications for clearing membership at OCC since most applicants for clearing membership choose to have their application presented for approval only when such approval is pro forma in nature (*i.e.*, the applicant meets all of the clearing membership requirements at OCC and there is no need to impose additional membership requirements). OCC believes that the proposed rule change will better allocate the time and resources of the Board and Risk Committee and ensure applications for clearing membership are considered in a timely manner.

Background

OCC believes that its membership criteria are objective standards that are designed not to unfairly discriminate in the admission of participants to OCC,[4] as well as to provide for fair and open access to OCC.[5] Currently, the authority to approve or disapprove new applications for clearing membership resides with the Board.[6] Under Article V, Section 2 of OCC's By-Laws, OCC's Risk Committee, including its designated delegates or agents, is responsible for reviewing applications for clearing membership, and the Risk Committee is responsible for making a recommendation of approval or disapproval to the Board (in part, relying on OCC's Management's review and recommendation).[7] OCC's management ("Management") performs the substantive review of applications for clearing membership on behalf of the Risk Committee. Management reviews a given application against OCC's membership criteria, which are set forth in Article V of OCC's By-Laws as well as Chapters 2 and 3 of OCC's Rules. Based on its review, Management, as the subject matter expert on OCC's membership criteria, either recommends an application for approval without conditions, recommends an application for approval with conditions (in accordance with OCC's By-Laws, Article V, Section 1, Interpretation and Policy .06), or does not recommend an application for approval. The Risk Committee, based on Management's review of the application, recommends a course of action to OCC's Board. OCC's Board then approves or disapproves applications for clearing membership based on the Risk Committee's recommendation.

Moreover, since the rules of the Commission and the Commodity Futures Trading Commission require OCC to have rules that do not unfairly discriminate in the admission of participants and provide fair and open access,[8] OCC believes that, under its rules, it is required to admit applicants for clearing membership that clearly meet OCC's membership criteria, and therefore, that the Board's ultimate approval of an application for clearing membership for which Management does not recommend approval with conditions or disapproval is pro forma. From a timing perspective, applications for clearing membership often do not track the Risk Committee or Board's regular meeting schedule and, on occasion, the Board has had to convene a special meeting for the sole purpose of considering an application for clearing membership or otherwise has had to seek approval via unanimous written consent, which OCC believes is an inefficient use of the Board's time and resources. In an effort to better allocate the time and resources of OCC's Board and Risk Committee as well as streamline its clearing membership approval process, OCC proposed the amendments to Articles V and VIII of its By-Laws as well as the Board and Risk Committee Charters described below. The effect of such amendments is that either OCC's Executive Chairman or President will approve most applications for clearing membership, thereby allowing the Board and the Risk Committee to better allocate their time and resources.

Changes to Vest Authority of New Applicant Approvals With the Risk Committee

OCC proposed amending Article V, Section 2 of its By-Laws to vest the authority to approve or disapprove new applicants for clearing membership with the Risk Committee. OCC believes that the members of the Board comprising the Risk Committee are capable of appropriately acting on membership applications. The Risk Committee is currently delegated the authority to (1) review applications for clearing membership and recommend approval or disapproval thereof to the Board, (2) conduct hearings if requested by applicants whose applications are proposed to be disapproved, and (3) review and approve or disapprove requests by clearing members to expand clearing activities.[9] Therefore, OCC believes that requiring the Board to approve or disapprove an application for clearing membership that has already been reviewed by, and received a recommendation for approval or disapproval from, the Risk Committee is redundant and represents an inefficient use of the Board's time. Accordingly, OCC believes that the Risk Committee is the appropriate governing body in which to vest ultimate authority to approve or disapprove applications for clearing membership.[10] Should the Risk Committee propose to disapprove an application for clearing membership, the Risk Committee must first provide the applicant an opportunity to be heard and present evidence on its own behalf (as is currently the case today with respect to the Board's decision to disapprove an application for clearing membership).[11]

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[3] OCC's Risk Committee is a committee of OCC's Board of Directors. *See* OCC's By-Laws Article III, Section 9.

[4] *See* 15 U.S.C. 78q–1(b)(3)(F).

[5] *See* 7 U.S.C. 7a–1(c)(2)(C)(iii)(III).

[6] *See* OCC's By-Laws Article V, Section 2.

[7] *See* OCC's By-Laws Article V, Section 2. The Risk Committee, from a practical perspective, has designated OCC's management as its agent to review applications for clearing membership. OCC's management reviews applications for clearing membership and makes a recommendation to the Risk Committee concerning the applicant's satisfaction of OCC's membership criteria.

[8] *See* 15 U.S.C. 78q–1(b)(3)(F) and 7 U.S.C. 7a–1(c)(2)(C).

[9] *See* Section IV of the Risk Committee Charter provided as Exhibit 5B to the proposed rule change.

[10] The Board will continue to oversee OCC's membership criteria and ongoing membership standards through its authority to approve changes to OCC's By-Laws and Rules (and specifically those By-Laws and Rules that concern membership). The Risk Committee will inform the Board, at the Board's next regularly scheduled meeting, of applications for clearing membership pursuant to proposed Article V, Section 2(c) of the By-Laws.

In order to effect the foregoing, and in addition to proposed changes to Article V, Section 2 of the By-Laws, OCC proposed conforming changes to Article V, Sections 1 and 3 of the By-Laws as well as the Board and Risk Committee Charters.[12] Such conforming changes identify that the Risk Committee, and not the Board, will approve applications for clearing membership. Additionally, OCC proposed changes to Article VIII, Section 2 of the By-Laws (as well as the Board and Risk Committee Charters) to identify that the Risk Committee, and not the Board, will set initial clearing fund requirements in connection with the approval of an application for clearing membership.

Delegation of Authority To Approve Applications for Membership to the Executive Chairman or President of OCC

OCC has stated that, in order to better streamline OCC's membership application approval process, and allow the Board and the Risk Committee to more efficiently allocate their time, it proposed additional amendments to Article V, Section 2 of its By-Laws to allow OCC's Executive Chairman or its President to approve certain applications for clearing membership. As described above: (i) OCC believes that, based on the applicable rules of the Commission and the Commodity Futures Trading Commission, applications for clearing membership that clearly meet OCC's membership criteria must be approved,[13] and (ii) applications for clearing members do not necessarily track the Risk Committee or Board's regular meeting schedule and, on occasion, the Board has had to convene in a special meeting for the sole purpose of considering a clearing member application or otherwise seek approval via unanimous written consent, which is not a good use of either the Board or the Risk Committee's time and resources. Therefore, OCC proposed amending Article V, Section 2 of its By-Laws to delegate the authority to approve applications for clearing membership to the Executive Chairman or President of OCC provided that: (i) It is not recommended that the Risk Committee impose additional membership criteria upon the applicant pursuant to Section 1, Interpretation and Policy .06 of Article V of OCC's By-Laws, and (ii) the Risk Committee is given not less than five business days from the date it is notified by its designated delegates or agents that the Executive Chairman or President intends to approve a given application to determine that such application should be reviewed at a meeting of the Risk Committee and the Risk Committee has not requested that the application be reviewed at a meeting of the Risk Committee within such five day period. If five business days pass and no member of the Risk Committee notifies Management that a given application for clearing membership should be reviewed at a meeting of the Risk Committee, then the Executive Chairman and President shall have the authority to approve the application for clearing membership. This proposed change will allow either OCC's Executive Chairman or the President to approve most applications for clearing membership received by OCC. Neither the Executive Chairman nor the President will be allowed to disapprove an application for clearing membership. Instead, if either the Executive Chairman or President determined he cannot approve an application for clearing membership, the application will be considered by the Risk Committee for approval or disapproval at its next regularly scheduled meeting. OCC believes that allowing the Executive Chairman or President to approve applications for clearing membership that clearly meet OCC's membership criteria will allow the Board and the Risk Committee to allocate their time to more efficiently and effectively.

II. Discussion

Section 19(b)(2)(C) of the Act[14] directs the Commission to approve a proposed rule change of a self-regulatory organization if it finds that the rule change, as proposed, is consistent with the requirements of the Act and the rules and regulations thereunder applicable to such organization.

The Commission finds that the proposed rule change is consistent with Section 17A(b)(3)(F)[15] of the Act. This section requires, among other things, that the rules of a clearing agency be designed to protect investors and the public interest while not being designed to permit unfair discrimination in the admission of participants. The proposed rule change will preserve Board-level oversight for the membership approval process by vesting the authority to approve or disapprove applications for clearing membership with the Risk Committee, a Board-level committee. A considerable portion of the Risk Committee's functions and responsibilities, as listed in its charter, pertains to the oversight of membership and membership standards generally. Therefore it is reasonable to expect that the Risk Committee should have the requisite expertise and authority to carry out the membership application approval or disapproval process previously tasked to the entire Board.

The proposed rules also delegate to the Executive Chairman or the President the authority to approve new applications provided that: (i) It is not recommended that the Risk Committee impose additional membership criteria upon the applicant pursuant to Section 1, Interpretation and Policy .06 of Article V of OCC's By-Laws, and (ii) the Risk Committee is given not less than five business days to determine that the application should be reviewed at a meeting of the Risk Committee and the Risk Committee has not requested that the application be reviewed at a meeting of the Risk Committee within such five day period. The authority to disapprove applications is not delegated to the Executive Chairman or the President. The rules, as revised, continue to provide Board-level oversight of the membership approval process by ensuring involvement of the Risk Committee. For the above reasons, although the revised rules will streamline the membership approval process, the Commission believes that they are designed to protect investors and the public interest. Additionally, the revised rules are not designed to permit unfair discrimination because they do not alter the criteria considered for the approval of new membership.

Additionally, the Commission finds that the revised rules are consistent with Rule 17Ad–22(d)(8) under the Act.[16] Rule 17Ad–22(d)(8) requires that a clearing agency establish, implement, maintain, and enforce written policies and procedures reasonably designed to, as applicable, have governance arrangements that are clear and transparent to fulfill the public interest requirements in Section 17A of the Act[17] applicable to clearing agencies and support the objectives of owners and participants. OCC's revised rules provide clarity and transparency in its governance processes by identifying, in OCC's public rulebook, the parties authorized to approve or disapprove membership applications, and fulfill the public interest requirements of Section 17A of the Act as described above.

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[11] *See* OCC's By-Laws Article V, Section 2. Typically, however, if OCC's due diligence review reveals issues that would prevent the Board or the Risk Committee from approving an application for clearing membership, the applicant voluntarily remediates such issues prior to the presentation of the application for clearing membership to the Risk Committee.

[12] Marked versions of the Board and Risk Committee Charters were provided as Exhibits 5A and 5B to the proposed change.

[13] *See* 15 U.S.C. 78q–1(b)(3)(F) and 7 U.S.C. 7a–1(c)(2)(C).

[14] 15 U.S.C. 78s(b)(2)(C).

[15] 15 U.S.C. 78q–1(b)(3)(F).

[16] 17 CFR 240.17Ad–22(d)(8).

[17] 15 U.S.C. 78q–1.

III. Conclusion

On the basis of the foregoing, the Commission finds that the proposal is consistent with the requirements of Act, and in particular, with the requirements of Section 17A of the Act[18] and the rules and regulations thereunder.

IT IS THEREFORE ORDERED, pursuant to Section 19(b)(2) of the Act,[19] that the proposed rule change (SR–OCC–2016–007) be, and it hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[20]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–16718 Filed 7–14–16; 8:45 am]

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[18] In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[19] 15 U.S.C. 78s(b)(2).

[20] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78289; File No. PCAOB–2007–04]

Public Company Accounting Oversight Board; Order Granting Approval of Proposed Amendments to Board Rules Relating to Inspections

July 11, 2016.

I. Introduction

On March 24, 2016, the Public Company Accounting Oversight Board (the "Board" or the "PCAOB") filed with the Securities and Exchange Commission (the "Commission"), pursuant to Section 107(b)[1] of the Sarbanes-Oxley Act of 2002 (the "Sarbanes-Oxley Act") and Section 19(b)[2] of the Securities Exchange Act of 1934 (the "Exchange Act"), a proposal to adopt amendments to Rule 4003, *Frequency of Inspections*, to revise paragraphs (b) and (d) and add new paragraphs (e) and (h) (collectively, the "Proposed Rules").[3] The Proposed Rules were published for comment in the **Federal Register** on April 13, 2016.[4] At the time the notice was issued, the Commission extended to July 12, 2016 the date by which the Commission should take action on the Proposed Rules.[5] The Commission received two comment letters in response to the notice.[6] This order approves the Proposed Rules.

II. Description of the Proposed Rules

On February 26, 2016, the Board adopted amendments to Rule 4003 to (i) require that at least five percent of registered public accounting firms that play a substantial role in the preparation or furnishing of an audit report be inspected on an annual basis, (ii) maintain the requirement to inspect all firms that issue an audit report for an issuer but provide the Board the discretion to forego an inspection, on a case-by-case basis, for a firm that does not subsequently issue an audit report for two consecutive years, (iii) qualify the term "audit report" to keep relevant portions of the rule consistent with the original meaning, and (iv) specify that no inspection requirement arises solely because a firm consented to an issuer's use of a previously issued audit report.

A. Amendments Related to the Inspection of Substantial Role Only Firms

Under the Proposed Rules, the triennial inspection requirement for registered public accounting firms that play a substantial role in audits but do not issue audit reports ("substantial role only")[7] is eliminated and replaced with a requirement to inspect at least five percent of such "substantial role only" firms. As a result, Rule 4003(b) is amended to delete the references to "substantial role only" firms and Proposed Rule 4003(h) is added to require that the Board will inspect at least five percent of the "substantial role only" firms on an annual basis. Additionally, Rule 4003(d) is amended to remove the references to "substantial role only" firms.

B. Amendments Related to the Inspections of Firms That Have Not Issued Audit Reports in Two Consecutive Years

Under the Proposed Rules, Rule 4003(b) will continue to retain the requirement to inspect any registered public accounting firm that issues an audit report with respect to an issuer. However, Proposed Rule 4003(e) is added to provide the Board with the discretion to forego the inspection of a registered public accounting firm that has not issued any audit reports in two consecutive years.

C. Amendments Related to the Term "Audit Report" and Consents to the Use of Previously Issued Audit Reports

Under the Proposed Rules, Rule 4003(d) is amended to add the phrase "with respect to an issuer" to qualify the term "audit report" within the rule. The added qualification is needed to clarify that the Proposed Rules apply only to the audits of issuers because, after the original rule was adopted, the Dodd-Frank Wall Street Reform and Consumer Protection Act ("Dodd-Frank Act")[8] amended the Sarbanes-Oxley Act to establish the PCAOB's oversight of the audits of broker-dealers.[9] Additionally, Rule 4003(b) is amended to provide that no inspection requirement arises under the rule solely because a firm consents to an issuer's use of a previously issued audit report.

D. Applicability and Effective Date

The Proposed Rules would become effective upon approval by the Commission and apply to the audits of all issuers, including audits of emerging growth companies ("EGCs"),[10] as discussed in Section IV below. The Proposed Rules do not impact the inspection frequency of the audits of brokers and dealers under Exchange Act Rule 17a–5.[11]

III. Comment Letters

As noted above, the Commission received two comment letters concerning the Proposed Rules. Both commenters expressed support for the Proposed Rules.[12]

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[1] 15 U.S.C. 7217(b).

[2] 15 U.S.C. 78s(b).

[3] On October 22, 2007, the Board filed amendments related to Rule 4003 with the Commission and requested Commission approval. The Commission did not act on the amendments subject to the 2007 filing. On February 26, 2016, the Board adopted revisions to those proposed amendments and, on March 24, 2016 amended the 2007 filing to reflect those revisions.

[4] *See* Release No. 34–77558 (April 7, 2016), 81 FR 21909 (April 13, 2016).

[5] Ibid.

[6] *See* letters from Deloitte Touche Tohmatsu Limited, dated April 29, 2016 ("Deloitte"), available at *https://www.sec.gov/comments/pcaob-2007-04/pcaob200704-1.pdf,* and an anonymous letter, dated May 3, 2016 ("anonymous letter"), available at *https://www.sec.gov/comments/pcaob-2007-04/pcaob200704-2.htm.*

[7] We are using the phrase "substantial role only" to identify the registered public accounting firms that play a substantial role in audits of issuers but do not issue audit reports with respect to any issuers as distinguished from the category of firms that play a substantial role in some audits and separately issue audit reports with regards to other audits. Firms that play a substantial role in an audit of an issuer must register with the PCAOB. *See* PCAOB Rule 2100(b).

[8] Public Law 111–203, 124 Stat. 1376 (2010).

[9] *See* Section 101 of the Sarbanes-Oxley Act [15 U.S.C. 7211].

[10] The term "emerging growth company" is defined in Section 3(a)(80) of the Exchange Act [15 U.S.C. 78c(a)(80)].

[11] If the broker or dealer is also an issuer, the Proposed Rules could impact the inspection frequency of the audits of such broker or dealer.

IV. The PCAOB's EGC Request

Section 103(a)(3)(C) of the Sarbanes-Oxley Act requires that any rules of the Board "requiring mandatory audit firm rotation or a supplement to the auditor's report in which the auditor would be required to provide additional information about the audit and the financial statements (auditor discussion and analysis)" shall not apply to an audit of an EGC.[13] The Proposed Rules do not fall into this category of rules. Section 103(a)(3)(C) further provides that "[a]ny additional rules" adopted by the PCAOB after April 5, 2012 shall not apply to the audits of EGCs "unless the Commission determines that the application of such additional requirements is necessary or appropriate in the public interest, after considering the protection of investors and whether the action will promote efficiency, competition, and capital formation." The Proposed Rules fall within this category of additional rules and thus the Commission must make a determination under the statute about the applicability of the Proposed Rules to audits of EGCs. Having considered those statutory factors, and as explained further herein, the Commission finds that applying the Proposed Rules to audits of EGCs is necessary or appropriate in the public interest.

In proposing application of the Proposed Rules to audits of all issuers, including EGCs, the Board requested that the Commission make the determination required by Section 103(a)(3)(C). To assist the Commission in making its determination under Section 103(a)(3)(C), the PCAOB prepared and submitted to the Commission its own EGC analysis, which was included in the Commission's public notice soliciting comment on the Proposed Rules. In its analysis, the Board states that the Proposed Rules do not change or add to the requirements that apply to the audits of any issuers, including EGCs. Any inspection of an audit of an EGC would be conducted in the same manner as it would have under existing PCAOB rules. The Proposed Rules only impact the frequency with which the PCAOB may inspect a small number of firms.[14]

The Board does not anticipate that the Proposed Rules would impact the audit quality for audits of EGCs by altering auditors' perception regarding inspection likelihood. Specifically, the Board does not believe that the Proposed Rules will affect an auditor's perception, during an audit of an EGC, of the possibility of such audit being inspected or the nature of any inspection or review, if conducted.

Based on the PCAOB's EGC analysis, we believe the information in the record is sufficient for the Commission to make the requested EGC determination in relation to the Proposed Rules. The Commission notes that because only a small number of firms fall within the categories of the Proposed Rules, the impact on the inspection frequency of the audits of EGCs is likely limited. Further, as to the "substantial role only" firms, the PCAOB is merely codifying its current practice.

V. Conclusion

The Commission has carefully reviewed and considered the Proposed Rules and the information submitted therewith by the PCAOB, including the PCAOB's EGC analysis, and the comment letters received. In connection with the PCAOB's filing and the Commission's review,

A. The Commission finds that the Proposed Rules are consistent with the requirements of the Sarbanes-Oxley Act and the securities laws and are necessary or appropriate in the public interest or for the protection of investors; and

B. Separately, the Commission finds that the application of the Proposed Rules to EGC audits is necessary or appropriate in the public interest, after considering the protection of investors and whether the action will promote efficiency, competition, and capital formation.

IT IS THEREFORE ORDERED, pursuant to Section 107 of the Sarbanes-Oxley Act and Section 19(b)(2) of the Exchange Act, that the Proposed Rules (File No. PCAOB–2007–04) be and hereby are approved.

By the Commission.

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2016–16727 Filed 7–14–16; 8:45 am]

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[12] *See* Deloitte letter and anonymous letter.

[13] 15 U.S.C. 7213(a)(3)(C).

[14] Specifically, out of the proposed amendments, only Proposed Rule 4003(e) would potentially change inspection frequency. However, the number of firms that would be covered by Proposed Rule 4003(e) appear to be small. The Board notes that there were 12 firms in 2015 that had previously issued an audit report in one year but none in the following two consecutive years. For the firms that would be covered by Proposed Rule 4003(h), the practice of the PCAOB has been to inspect five percent of those firms on an annual basis since 2009.

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78283; File No. SR–NYSEMKT–2016–42]

Self-Regulatory Organizations; NYSE MKT LLC; Notice of Filing of Amendment No. 1 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment No. 1, To Amend Rule 952NY With Respect to Opening Trading in an Options Series

July 11, 2016.

I. Introduction

On March 23, 2016, NYSE MKT LLC ("Exchange") filed with the Securities and Exchange Commission ("Commission"), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")[1] and Rule 19b–4 thereunder,[2] a proposed rule change to amend Exchange Rule 952NY regarding the process for opening trading in an options series. The proposed rule change was published for comment in the **Federal Register** on April 12, 2016.[3] On May 25, 2016, the Commission extended the time period within which to approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to disapprove the proposed rule change to July 11, 2016.[4] On July 8, 2016, the Exchange submitted Amendment No. 1 to the proposed rule change.[5] The Commission received no comment letters on the proposed rule change. The Commission is publishing this notice to solicit comment on Amendment No. 1 to the proposed rule change from interested persons and is approving the proposed rule change, as modified by Amendment No. 1, on an accelerated basis.

II. Description of the Proposed Rule Change, as Modified by Amendment No. 1

Exchange Rule 952NY sets forth the Exchange System's automated opening process.[6] Current Rule 952NY(b) provides that, after the primary market for the underlying security disseminates an opening trade or an opening quote, the Exchange will open the related option series automatically based on the following principles and procedures:

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[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 77540 (April 6, 2016), 81 FR 21623 ("Notice").

[4] *See* Securities Exchange Act Release No. 77911 (May 25, 2016), 81 FR 35115 (June 1, 2016).

[5] *See* Letter to Brent J. Fields, Secretary, Commission, from Martha Redding, Associate General Counsel, Assistant Secretary, NYSE MKT, LLC dated July 11, 2016. As more fully described below, in Amendment No. 1 the Exchange proposes additional modifications to Rule 952NY(c) to clarify and detail how the Exchange would determine the opening price upon dissemination of an NBBO from OPRA.

[6] *See* Exchange Rule 952NY. The term "System" refers to the Exchange's electronic order delivery,

(A) The system will determine a single price at which a particular option series will be opened.

(B) Orders and quotes in the system will be matched up with one another based on price-time priority; provided, however, that Orders will have priority over Market Maker quotes at the same price.

(C) Orders in the System Book that were not executed during the Auction Process shall become eligible for the Core Trading Session immediately after the conclusion of the Auction Process.

(D) The System will not conduct an Auction Process if the bid-ask differential for that series is not within an acceptable range. For the purposes of this rule, an acceptable range shall mean within the bid-ask differential guidelines established pursuant to Rule 952NY(b)(4).

(E) If the System does not open a series with an Auction Process, the System shall open the series for trading after receiving notification of an initial NBBO disseminated by OPRA for the series or on a Market Maker quote, provided that the bid-ask differential does not exceed the bid-ask differential specified under Rule 952NY(b)(5).[7]

In addition, Rule 952NY(c) provides for how the System will determine the opening price of a series when an Auction Process is conducted.[8] Specifically, current Rule 952NY(c) states, in part, that the "opening price of a series will be the price, as determined by the System, at which the greatest number of contracts will trade at or nearest to the midpoint of the initial uncrossed NBBO disseminated by OPRA, if any, or the midpoint of the best quote bids and quote offers in the System Book." [9]

The Exchange proposes several changes to Exchange Rule 952NY and the System opening process. The proposed changes would also affect the process of re-opening an options series after a trading halt.[10]

First, the Exchange proposes to amend Exchange Rule 952NY(b) so that trading in an options series will be opened automatically once the primary market for the underlying security disseminates both a quote and a trade that is at or within the quote.[11] Further, the Exchange proposes to specify that the opening process will occur at or after 9:30 a.m. Eastern Time.[12]

The Exchange also proposes to modify Exchange Rule 952NY(b)(E) so that if the System does not open a series with an Auction Process, trading in an options series could no longer open on a local Market Maker quote, but would instead require an initial uncrossed NBBO disseminated by OPRA.[13] According to the Exchange, OPRA disseminates an NBBO based on information collected from the exchanges.[14] Thus, the Exchange states, NYSE MKT's local Market Maker quotes would be disseminated back to the Exchange from OPRA and may or may not be at the same price as the NBBO.[15]

In addition, the Exchange proposes to amend Rule 952NY(c). As noted, current Rule 952NY(c) provides that if there is no initial uncrossed NBBO disseminated by OPRA, the System instead determines an opening price that is "at the midpoint of the best quotes and offers in the System Book." The Exchange originally proposed to modify Rule 952NY(c) by eliminating this language so that the rule would no longer provide that the opening price of a series could be determined by reference to the best quote bids and offers in the System Book.[16] Thus, as originally proposed, the opening price of a series would be the price, as determined by the System, at which the greatest number of contracts will trade "at or nearest to the midpoint of the initial uncrossed NBBO disseminated by OPRA." [17] As more fully set forth in the Notice, the Exchange stated that the original proposed modification was a conforming change that was necessary because the Exchange would no longer open solely on a local Market Maker quote.[18]

In Amendment No. 1, the Exchange proposes further modifications to Rule 952NY(c) to clarify and detail how the Exchange would determine the opening price upon dissemination of an NBBO from OPRA. Under proposed 952NY(c), as modified by Amendment No. 1, "[t]he opening price of a series will be the price, as determined by the System, at which the greatest number of contracts will trade at a price at or between the NBBO disseminated by OPRA." [19] In addition, in Amendment No. 1 the Exchange proposes to specify further the circumstances under which the System would use midpoint pricing.[20] In particular, proposed Rule 952NY(c), as modified by Amendment No. 1, would specify what would happen if there is a tie and the same number of contracts can trade at multiple prices. Specifically, proposed Rule 952NY(c), as modified by Amendment No. 1, would provide that if the same number of contracts can trade at multiple prices, the opening price is the price at which the greatest number of contracts can trade that is "at or nearest to the midpoint" of the NBBO disseminated by OPRA. The rule would further specify that (i) if one of such prices is equal to the price of any Limit Order(s) in the Consolidated Book, the opening price will be the same price as the Limit Order(s) with the greatest size and, if the same size, the highest price; and (ii) if there is a tie between price levels and no Limit Orders exist at either of the prices, the Exchange would use the higher price.[21] In connection with these proposed modifications, the Exchange further proposes to delete language in current Rule 952NY(c) referring to pricing by reference to the best quotes bids and offers in the System. According to the Exchange, the language proposed to be deleted is superfluous, as the Exchange would no longer use Market Maker quotes to determine the opening price.[22]

Finally, the Exchange proposes a new provision to permit the Exchange to deviate from the standard manner of the Auction Process, including adjusting the timing of the Auction Process in any option class, when the Exchange believes it to be necessary in the interest of a fair and orderly market.[23]

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execution and reporting system through which orders and quotes for listed options are consolidated for execution and/or display. *See* Exchange Rule 900.2NY(48) (defining "Exchange System" or "System").

[7] *See* Exchange Rule 952NY(b)(A)–(E).

[8] *See* Notice and current Exchange Rule 952NY(c).

[9] *See* current Exchange Rule 952NY(c).

[10] *See* Exchange Rule 952NY(a), which provides that the Exchange will follow the same procedures in opening after a trading halt as the procedures followed for the opening of the trading day.

[11] *See* proposed Rule 952NY(b).

[12] *See id.*

[13] *See* proposed Rule 952NY(b)(E).

[14] *See* Notice, *supra* note 3, at 21624.

[15] *See* Notice, *supra* note 3, at 21624.

[16] Specifically, the Exchange proposed to delete from current 952NY(c) the words "if any, or the midpoint of the best quotes and offers in the System Book."

[17] *See* Notice *supra* note 3 at 21624.

[18] *See id.*

[19] *See* Amendment No. 1 and proposed Rule 952NY(c).

[20] *See* Amendment No. 1 and proposed Rule 952NY(c).

[21] *See* Amendment No. 1 and proposed Rule 952NY(c).

[22] *See* Amendment No. 1 and proposed Rule 952NY(c).

[23] *See* proposed Rule 952NY(b)(F); *see also* Notice, *supra* note 3, at 21624. For a more detailed description of the original proposed rule change, *see* Notice, *supra* note 3.

III. Discussion and Commission Findings

After careful review, the Commission finds that the proposed rule change, as modified by Amendment No. 1, is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.[24] In particular, the Commission finds that the proposed rule change, as modified by Amendment No. 1, is consistent with Section 6(b)(5) of the Act,[25] which requires, among other things, that the rules of a national securities exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.

The Commission believes the Exchange's proposal to require both a disseminated quote and a trade within the quote in an underlying security before opening trading in the related options series, instead of either one or the other, is reasonably designed ensure that the underlying security has been opened pursuant to a robust price discovery process before the overlying option begins trading.[26]

The Exchange proposes that if it does not open a series with an Auction Process, it will open the series for trading after receiving notification of an initial uncrossed NBBO disseminated by OPRA.[27] The Exchange represents that opening an options series for trading after receiving an uncrossed NBBO from OPRA, rather than based on a local Market Maker quote, will eliminate ambiguity as to the source of the information for each options series and should lead to more accurate prices on the Exchange.[28]

Further, the Exchange proposes that if it does open a series with an Auction Process, the opening price of a series will be the price, as determined by the System, at which the greatest number of contracts will trade at a price at or between the NBBO disseminated by OPRA. The Exchange further proposes to specify how the System will determine an opening price if the same number of contracts can trade at multiple prices.[29] The Commission believes the proposed process for how the System will determine an opening price for an option series at or between the NBBO disseminated by OPRA, and the circumstances under which System would use midpoint pricing, should result in an opening price that is related to the current market for an option and is therefore reasonably designed to protect investors and the public interest.

In addition, the Commission believes it is appropriate to allow the Exchange the discretion to deviate from the standard manner of the Auction Process, as the proposal provides, when it believes it is necessary in the interests of a fair and orderly market. The Commission believes that the ability to exercise such discretion can be important in situations when, for example, the primary market for an options class is unable to open due to a systems or technical issue or if some other unanticipated circumstance arises. The Commission notes that it has previously approved provisions of this kind as consistent with the Act.[30]

The Commission further believes that the proposed rule change will provide transparency and enhance investors' understanding of the operation of the Exchange's opening process. For these reasons, the Commission believes that the proposed rule change, as modified by Amendment No. 1, is consistent with the Act.

IV. Solicitation of Comments on Amendment No. 1

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether Amendment No. 1 to the proposed rule change is consistent with the Exchange Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–NYSEMKT–2016–42 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEMKT–2016–42. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEMKT–2016–42 and should be submitted by August 5, 2016.

V. Accelerated Approval of Proposed Rule Change, as Modified by Amendment No. 1

The Commission finds good cause to approve the proposed rule change, as modified by Amendment No. 1, prior to the 30th day after the date of publication of notice of Amendment No. 1 in the **Federal Register**. As discussed above, Amendment No. 1 clarifies how the Exchange would determine the opening price upon dissemination of an NBBO from OPRA, an in particular specifies the circumstances in which "at or nearest to the midpoint" pricing is utilized during the Auction Process. Furthermore, the Commission believes it is appropriate to have these changes incorporated into the rules of the Exchange concurrently with the changes discussed in the original filing.

Accordingly, the Commission finds good cause, pursuant to Section 19(b)(2) of the Exchange Act,[31] to approve the proposed rule change, as modified by

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[24] In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[25] 15 U.S.C. 78f(b)(5).

[26] *See* Notice, *supra* note 3, at 21624.

[27] *See supra* note 13 and accompanying text.

[28] *See* Notice, *supra* note 3, at 21624.

[29] *See supra* note 20 and accompanying text.

[30] *See, e.g.*, Securities Exchange Act Release No. 71651 (March 5, 2014), 79 FR 13693 (March 11, 2014) (SR–BATS–2014–003).

[31] 15 U.S.C. 78s(b)(2).

Amendment No. 1 on an accelerated basis.

VI. Conclusion

IT IS THEREFORE ORDERED, pursuant to Section 19(b)(2) of the Exchange Act,[32] that the proposed rule change (SR–NYSEMKT–2016–42), as modified by Amendment No. 1 thereto, be, and it hereby is, approved on an accelerated basis.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[33]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–16723 Filed 7–14–16; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78285; File No. SR–NASDAQ–2016–087]

Self-Regulatory Organizations; The NASDAQ Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to Automated Removal of Orders and Quotes

July 11, 2016.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on June 30, 2016, The NASDAQ Stock Market LLC ("Nasdaq" or "Exchange") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the rules of the NASDAQ Options Market LLC ("NOM") at Chapter VII, Section 6(f), entitled "Automated Removal of Orders and Quotes."

The text of the proposed rule change is available on the Exchange's Web site at *http://nasdaq.cchwallstreet.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend a NOM Rule at Chapter VII, Section 6(f), entitled "Automated Removal of Orders and Quotes" to modify the minimum Specified Percentage (as described below). A NOM Market Maker[3] sets the Specified Percentage to enhance its risk management for an underlying security as market conditions warrant, based on its own risk tolerance level and quoting behavior. The Exchange proposes to permit the NOM Market Maker to set the Specified Percentage more broadly, no less than 1% with this rule change. The Exchange also proposes to replace the term "disseminated size"[4] with a quantitative description to add transparency with respect to the calculation of Series Percentage.

Background

Today, Chapter VII, Section 6(f) permits NOM Market Makers to monitor risk arising from multiple executions across multiple options series of a single underlying security. A NOM Market Maker may provide a specified time period and a specified percentage by which the Exchange's System will automatically remove a NOM Market Maker's quotes and orders in all series of an underlying security submitted through designated NOM protocols, as specified by the Exchange, during a specified time period not to exceed 15 seconds ("Percentage-Based Specified Time Period.").[5]

For each series in an option, the System determines: (i) The percentage that the number of contracts executed in that series represents relative to the NOM Market Maker's disseminated size of each side in that series ("Series Percentage"); and (ii) the sum of the Series Percentage in the option issue ("Issue Percentage"). The Exchange proposes herein to replace the term "disseminated size" with the more precise phrase "number of contracts available at the time of execution plus the number of contracts executed in unexpired prior executions."

The System tracks and calculates the net impact of positions in the same option issue during the Percentage-Based Specified Time Period. Specifically, the System tracks transactions, *i.e.,* the sum of buy-side put percentages, the sum of sell-side put percentages, the sum of buy-side call percentages, and the sum of sell-side call percentages. The System then calculates the absolute value of the difference between the buy-side puts and the sell-side puts plus the absolute value of the difference between the buy-side calls and the sell-side calls. If the Issue Percentage, rounded to the nearest integer, equals or exceeds a percentage established by the NOM Market Maker, not less than 100% ("Specified Percentage"), the System automatically removes a NOM Market Maker's quotes and orders in all series of an underlying security submitted through designated NOM protocols, as specified by the Exchange, during the Percentage-Based Specified Time.

The Percentage-Based Specified Time Period commences for an option every time an execution occurs in any series in such option and continues until the System removes quotes and orders as described in Chapter VII, Section 6(f)(iv) or (v) or the Percentage-Based Specified Time Period expires. The Percentage-Based Specified Time Period operates on a rolling basis among all series in an option in that there may be multiple Percentage-Based Specified Time Periods occurring simultaneously and such Percentage-Based Specified Time periods may overlap.

Proposal

The Exchange proposes to lower the minimum Specified Percentage, which is set by the NOM Market Maker, from 100% to 1%. The proposal would amend the rule text to state, if the Issue Percentage, rounded to the nearest integer, equals or exceeds a percentage established by the NOM Market Maker, not less than *1%* ("Specified Percentage"), the System automatically removes a NOM Market Maker's quotes and orders in all series of an underlying security submitted through designated NOM protocols, as specified by the Exchange, during the Percentage-Based Specified Time. This proposal would allow a NOM Market Maker to establish a Specified Percentage at any percentage level greater than or equal to 1% for an option in which the NOM Market Maker is appointed. Today, the Specified Percentage would be set by the NOM Market Maker at greater than or equal to 100%. This amendment will allow NOM Market Makers to better manage their risk and assist them to avoid trading a number of contracts that exceeds the NOM Marker Maker's risk tolerance level across multiple series of a single underlying when such series are executed in rapid succession.

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[32] 15 U.S.C. 78s(b)(2).

[33] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The term "Nasdaq Options Market Maker" or "Options Market Maker" (herein "NOM Market Maker") means an Options Participant registered with the Exchange for the purpose of making markets in options contracts traded on the Exchange and that is vested with the rights and responsibilities specified in Chapter VII of these Rules. *See* NOM Rules at Chapter I, Section 1(a)(26).

[4] *See* Securities Exchange Act Release No 76316 (October 30, 2015), 80 FR 68595 at 68597 (November 5, 2015) (SR–NASDAQ–2015–122). The Exchange defined disseminated size in this rule change in footnote 13, as the original size quoted by the Participant.

[5] A specified time period commences for an option when a transaction occurs in any series in such option.

NOM Market Makers will be able to more precisely customize their risk settings within the System. NOM Market Makers will be able to consider factors such as present and anticipated market conditions, news in an option, and a sudden change in volatility of an option. NOM Market Makers are required to utilize either the Percentage Based Threshold or the Volume Based Threshold. NOM Market Makers that select to utilize the Percentage-Based Threshold will be able to adopt more precise controls with this proposal based on the NOM Market Maker's risk tolerance level.

NOM Market Makers must utilize either the Percentage-Based[6] or Volume-Based risk controls. NOM Market Makers may contact Market Operations to set their percentage, which is 1% or greater with this proposal, and specified time period.

By way of example, if a NOM Market Maker has set the percentage setting to 50% and a Specified Time Period of 15 seconds and the Order Book reflects:

MM1 has a displayed quote of 1.10 (100) × 1.20 (100) for IBM May 20, 2016 70 puts and MM1 is the only displayed size on NOM and an order is submitted to buy 75 IBM May 20, 2016 70 Puts for 1.20.

Chapter VII, Section 6(f) would cause the following:

(1) Provide MM1 with an execution—Sold 75 @ 1.20; and

(2) Trigger the Percentage-Based Threshold and remove MM1's quotes in IBM.

Another example is with multiple executions. Presume the following:

MM1 has set the percentage to 80% by 5 seconds and MM1 has a displayed quote of 2.00 (100) × 2.25 (100) for IBM May 20, 2016 70 puts and he is the only displayed size on the NOM. Also, presume an order comes in to buy 50 IBM May 20, 2016 70 puts for 2.25.

Chapter VII, Section 6(f) would cause the following:

(1) Provide MM1 with an execution—Sold 50 @ 2.25;

(2) Update MMI [sic] quote to 2.00 (100) × 2.25 (50);

(3) Within 1 second an order comes in to buy 45 IBM May 20, 2016 70 puts for 2.25;

(4) Provide MM1 with an execution—Sold 45 @ 2.25; and

(5) Trigger the Percentage-Based Threshold and remove MM1's quotes in IBM.

The Exchange also proposes to replace the term "disseminated size" with a quantitative description to add transparency with respect to the calculation of Series Percentage. The language proposed amends the original definition of disseminated size. With respect to the disseminated size, the Exchange previously defined disseminated size as ". . . the original size quoted by the Participant."[7]

The Exchange proposes to amend the definition as follows: "For each series in an option, the System will determine: (i) The percentage that the number of contracts executed in that series represents relative to the number of contracts available at the time of execution plus the number of contracts executed in unexpired prior executions of each side in that series ("Series Percentage"); and (ii) the sum of the Series Percentage in the option issue ("Issue Percentage")." The Exchange counts Specialized Quote Feed ("SQF")[8] quotes and OUCH To Trade Options ("OTTO")[9] orders only in determining the number of contracts traded and removed by the System. OTTO orders are single sided and may be submitted at multiple price levels for each series, whereas SQF permits a two-sided quote for each NOM Market Maker. The calculation considers the different price levels.

By way of example, with the proposed definition, if a NOM Market Maker with a Percentage-Based Specified Time Period of 10 seconds and a Specified Percentage of 100% submits a quote over SQF of 1.00(100) × 1.10(100) and a buy order executes 75, the remaining size would be 1.00(100) × 1.10(25). Thereafter a new Percentage-Based Specified Time Period begins and current Series Percentage executed is 75 and three seconds pass and the NOM Market Maker re-quotes 1.00(100) × 1.10 (100), an incoming buy order of 43 would cause the Issue Percentage to meet the Percentage-Based Threshold. This is due to a counted size of 175 (the executed 75 plus the newly quoted 100) and rounding (0.75 + 43/175 = 0.9957 rounds up to 100%). If the former definition applied, the size would have been 100 and an execution of only 25 contracts on the same side would have caused the Issue Percentage to meet the Percentage-Based Threshold, which is not the case. In other words, the current SQF quote and all OTTO orders on that side for that series (for that NOM Market Maker) in addition to all the executions that have occurred on that side for that series (for that NOM Market Maker) within the Percentage-Based Specified Time Period would comprise the size.

This new definition accurately represents the manner in which the Issue Percentage is calculated. Also, the more precise language within the rule text will provide NOM Market Makers with a more accurate description of the operation of this risk mechanism. The Exchange has always calculated the NOM Market Maker's size in this fashion. The definition, as described in the prior rule change, was not accurate and the Exchange seeks to amend the definition with this proposal and memorialize the definition within the rule.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act[10] in general, and furthers the objectives of Section 6(b)(5) of the Act[11] in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest, by offering NOM Market Makers the ability to better manage their own risk with this risk feature.

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[6] NOM Market Makers selecting the Percentage-Based risk control in Chapter VII, Section 6(f)(i) are required to provide a specified time period, up to 15 seconds, and a specified percentage with a number of 1% or greater, as proposed herein, to the NOM Market Operations staff to select this risk control. If a NOM Market Maker does not desire to utilize the Percentage-Based risk control the NOM Market Maker must utilize the Volume-Based risk control which is similarly set-up by contacting Market Operations and providing certain settings.

[7] *See* note 4 above.

[8] SQF permits the receipt of quotes. SQF Auction Responses and market sweeps are also not included.

[9] OTTO provides a method for subscribers to send orders and receive status updates on those orders. OTTO accepts limit orders from System subscribers, and if there is a matching order, the orders will execute. Non-matching orders are added to the limit order book. All NOM Participants have the ability to utilize OTTO. OTTO immediate or cancel orders will not be included.

[10] 15 U.S.C. 78f(b).

[11] 15 U.S.C. 78f(b)(5).

NOM Market Makers are obligated to submit continuous two-sided quotations in a certain number of series in their appointed option classes for a certain percentage of each trading session.[12] This obligation renders them vulnerable to risk from unusual market condition, volatility in specific options, and other market events that may cause them to receive multiple, extremely rapid automatic executions before they can adjust their quotations and overall risk exposure in the market. Without adequate risk management tools in place on the Exchange, the incentive for NOM Market Makers to quote aggressively, respecting both price and size could be diminished. Such a result may undermine the quality of the markets, which are enhanced by the depth and liquidity such NOM Market Makers provide in the marketplace.

By allowing the Specified Percentage provided by the NOM Market Maker to be reduced from 100% to 1%, the Exchange provides its NOM Market Makers the desired flexibility to take into account such factors as present and anticipated market conditions, news in an option or sudden change in volatility of an option without any limitation regarding the Specified Percentage. This should encourage NOM Market Makers to provide additional depth and liquidity to the Exchange's markets, thereby removing impediments to and perfecting the mechanisms of a free and open market and a national market system and, in general, protecting investors and the public interest.

The proposal is consistent with the Act because the reduction of the Specified Percentage to not less than 1% provides more alternatives to NOM Market Makers in setting their percentage without impacting their firm quote obligations. The System operates consistently with the firm quote obligations of a broker-dealer pursuant to Rule 602 of Regulation NMS. Specifically, with respect to NOM Market Makers, their obligation to provide continuous two-sided quotes on a daily basis is not diminished by the removal of such quotes and orders by the Percentage-Based Threshold. NOM Market Makers are required to provide continuous two-sided quotes on a daily basis.[13] NOM Market Makers that utilize the Percentage-Based Threshold will not be relieved of the obligation to provide continuous two-sided quotes on a daily basis, nor will the change prohibit the Exchange from taking disciplinary action against a NOM Market Maker for failing to meet the continuous quoting obligation each trading day. All quotes entered into the System are considered firm. Quotes will only be removed from the System once the Percentage-Based Threshold has been met if the quote was not otherwise executed by an incoming order.

This risk feature will continue to remove impediments to and perfect the mechanism of a free and open market and a national market system and protect investors and the public interest by allowing NOM Market Makers to remove their quotes and orders in the event that market conditions warrant, based on their own risk tolerance level. NOM Market Makers provide liquidity to the market place and have obligations unlike other market participants.[14] This risk feature is important because it will enable NOM Market Makers to manage their exposure at the Exchange. Further, permitting NOM Market Makers to enter a broader setting would continue to allow NOM Market Makers to have flexibility in setting their risk exposure to prevent unintended triggers of the Percentage-Based Threshold. This proposal continues to allow NOM Market Makers to select a Percentage-Based Specified Time Period. Each NOM Market Maker has different levels of sensitivity and its own system safeguards as well. The proposed setting would permit each NOM Market Maker to select a setting that is appropriate to capture the needs of that NOM Market Maker.

Further, it is important to note that any interest that is executable against a NOM Market Maker's quotes and orders that are received[15] by the Exchange prior to the trigger of the Percentage-Based Threshold, which is processed by the System, automatically executes at a price up to the NOM Market Maker's size. The system-generated Purge Notification Message is accepted by the System in the order of receipt in the queue and is processed in that order so that interest that is already accepted into the System is processed prior to the message. Incoming orders received prior to the Purge Notification Message would not be cancelled, rather they be [sic] executed at a price up to the NOM Market Maker's size.

The Exchange notes that Miami International Securities Exchange, LLC ("MIAX") implemented a rule that changed its Allowable Engagement Percentage from a minimum of 100% to any percentage established by the Market Maker.[16] The NOM rule is similar to MIAX's in that a member is required to have a setting, although MIAX has a default setting in place in the instance that no percentage is provided. NOM Market Makers that select the Percentage-Based risk tool must provide the Exchange with a Percentage-Based Specified Time Period greater than or equal to 1%. [sic] Amending the definition of disseminated size will provide market participants with greater information on the manner in which the Exchange computes the Issue Percentage. The Exchange believes that the manner in which the Exchange calculates the number of contracts, which are counted for the Issue Percentage, is consistent with the Act. The counting method permits the Exchange to update the reference number to include the executed contracts. While this method differs from the method previously described, the Exchange believes that there is no industry standard for counting and its method permits market participants to achieve the desire [sic] risk protection. With the proposed definition, each execution uses the Percentage-Based Specified Time Period that existed at the time of the execution. NOM Market Makers can change the Percentage-Based Specified Time Period at any time. If a NOM Market Maker is using a Percentage-Based Specified Time Period of 15 seconds when an execution happens, then changes the Percentage-Based Specified Time Period to half a second, that first execution will not expire until 15 seconds have passed. The selected Percentage-Based Specified Time Period will persist for 15 seconds and the number of executed contracts will be included in the denominator of subsequent executions for a full 15 seconds.

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[12] Pursuant to NOM Rules at Chapter VII, Section 5, entitled "Obligations of Market Makers", in registering as a market maker, an Options Participant commits himself to various obligations. Transactions of a NOM Market Maker must constitute a course of dealings reasonably calculated to contribute to the maintenance of a fair and orderly market, and Market Makers should not make bids or offers or enter into transactions that are inconsistent with such course of dealings. Further, all Market Makers are designated as specialists on NOM for all purposes under the Act or rules thereunder. *See* Chapter VII, Section 5.

[13] *Id.*

[14] *Id.*

[15] The time of receipt for an order or quote is the time such message is processed by the Exchange book.

[16] *See* Securities Exchange Act Release No. 77817 (May 12, 2016), 81 FR 31286 (May 18, 2016) (SR–MIAX–2016–10).

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The Percentage-Based Threshold is intended to protect NOM Market Makers from exposure to excessive risk. The Exchange believes this proposal will foster competition by providing NOM Market Makers with the ability to enhance and customize their percentage in order to compete for executions and order flow. Specifically, the proposal does not impose a burden on intra-market or inter-market competition; rather, it provides NOM Market Makers with the opportunity to avail themselves of similar risk tools, which are currently available on other exchanges.[17] NOM Market Makers quote across many series in an option creating the possibility of "rapid fire" executions that can create large, unintended principal positions that expose NOM Market Makers. The Percentage-Based Threshold permits NOM Market Makers to monitor risk arising from multiple executions across multiple options series of a single underlying security.

The Exchange is proposing this rule change to continue to permit NOM Market Makers to reduce their risk in the event the NOM Market Maker is suffering from a system issue or due to the occurrence of unusual or unexpected market activity. Reducing such risk will enable NOM Market Makers to enter quotations without any fear of inadvertent exposure to excessive risk, which in turn will benefit investors through increased liquidity for the execution of their orders. Reducing risk by utilizing the proposed risk protections enables NOM Market Makers, specifically, to enter quotations with larger size, which in turn will benefit investors through increased liquidity for the execution of their orders. Such increased liquidity benefits investors because they receive better prices and because it lowers volatility in the options market.

The Exchange believes that amending the definition of disseminated size does not create an undue burden on competition because the Exchange will uniformly calculate the Percentage-Based Threshold in a uniform manner for all NOM Market Makers. The Exchange is memorializing the definition within the Rule.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act[18] and Rule 19b–4(f)(6) thereunder.[19] The Exchange has requested that the Commission waive the thirty-day operative delay so that the proposal may become operative immediately. The Commission believes that waiving the thirty-day operative delay is consistent with the protection of investors and the public interest. The Exchange proposes to change a setting in an existing risk protection feature to enhance market makers' ability to protect against excessive risk arising from multiple executions across multiple options series of a single underlying security. The Commission notes that another options exchange currently has a similar setting for a like risk protection feature for market makers. Moreover, the Commission notes that the proposal to replace the term "disseminated size" with an accurate and more precise description would add transparency with respect to the operation of the risk protection feature. Therefore, the Commission hereby waives the thirty-day operative delay and designates the proposal operative upon filing.[20]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NASDAQ–2016–087 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NASDAQ–2016–087. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NASDAQ–2016–087 and should be submitted on or before August 5, 2016.

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[17] *See* Section 8 of the 19b4.

[18] 15 U.S.C. 78s(b)(3)(A).

[19] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and the text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[20] For purposes of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[21]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–16724 Filed 7–14–16; 8:45 am]

BILLING CODE 8011–01–P

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[21] 17 CFR 200.30–3(a)(12).

SURFACE TRANSPORTATION BOARD

[Docket No. AB 290 (Sub-No. 383X)]

Norfolk Southern Railway Company—Discontinuance of Service Exemption—In Shenandoah County, VA

Norfolk Southern Railway Company (NSR) has filed a verified notice of exemption under 49 CFR part 1152, subpart F—*Exempt Abandonments and Discontinuance of Service* to discontinue service over an approximately 16.9-mile rail line extending from milepost B 62.0 (at Strasburg, VA) to milepost B 78.9 (near Edinburg, VA) in Shenandoah County, VA (the Line). The Line traverses United States Postal Service Zip Codes 22657, 22660, 22644, 22664, and 22824.

NSR has certified that: (1) No local traffic has moved over the Line for at least two years; (2) because the Line is not a through route, no overhead traffic has operated, and, therefore, none needs to be rerouted over other lines; (3) no formal complaint filed by a user of rail service on the Line (or by a state or local government entity acting on behalf of such user) regarding cessation of service over the Line is pending either with the Surface Transportation Board (Board) or with any U.S. District Court or has been decided in favor of complainant within the two-year period; and (4) the requirements at 49 CFR 1105.12 (newspaper publication) and 49 CFR 1152.50(d)(1) (notice to governmental agencies) have been met.

As a condition to this exemption, any employee adversely affected by the discontinuance of service shall be protected under *Oregon Short Line Railroad—Abandonment Portion Goshen Branch Between Firth & Ammon, in Bingham & Bonneville Counties, Idaho*, 360 I.C.C. 91 (1979). To address whether this condition adequately protects affected employees, a petition for partial revocation under 49 U.S.C. 10502(d) must be filed.

Provided no formal expression of intent to file an offer of financial assistance (OFA) to subsidize continued rail service has been received, this exemption will be effective on August 16, 2016, unless stayed pending reconsideration. Petitions to stay that do not involve environmental issues and formal expressions of intent to file an OFA to subsidize continued rail service under 49 CFR 1152.27(c)(2)[1] must be filed by July 25, 2016.[2] Petitions to reopen must be filed by August 4, 2016, with the Surface Transportation Board, 395 E Street SW., Washington, DC 20423–0001.

A copy of any petition filed with the Board should be sent to NSR's representative: William A. Mullins, Baker & Miller PLLC, 2401 Pennsylvania Ave. NW., Suite 300, Washington, DC 20037.

If the verified notice contains false or misleading information, the exemption is void ab initio.

Board decisions and notices are available on our Web site at *WWW.STB.DOT.GOV.*

Decided: July 12, 2016.

By the Board, Rachel D. Campbell, Director, Office of Proceedings.

Raina S. Contee,

Clearance Clerk.

[FR Doc. 2016–16773 Filed 7–14–16; 8:45 am]

BILLING CODE 4915–01–P

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[1] Each OFA must be accompanied by the filing fee, which is currently set at $1,600. *See* 49 CFR 1002.2(f)(25).

[2] Because this is a discontinue proceeding and not an abandonment, interim trail use/rail banking and public use conditions are not appropriate. Because there will be an environmental review during abandonment, this discontinuance does not require an environmental review.

SURFACE TRANSPORTATION BOARD

[Docket No. FD 36029]

Watco Holdings, Inc.—Continuance in Control Exemption—Kanawha River Railroad, LLC

Watco Holdings, Inc. (Watco), a noncarrier, has filed a verified notice of exemption pursuant to 49 CFR 1180.2(d)(2) to continue in control of Kanawha River Railroad, LLC (KNWA), upon KNWA's becoming a Class III rail carrier. Watco owns, indirectly, 100% of the issued and outstanding stock of KNWA, a limited liability company.[1]

This transaction is related to a concurrently filed verified notice of exemption in *Kanawha River Railroad, L.L.C.—Lease Exemption Containing Interchange Commitment—Norfolk Southern Railway Company,* Docket No. FD 36028, wherein KNWA seeks Board approval to lease and operate approximately nine rail segments, totaling 308.85 miles of rail line from the Norfolk Southern Railway Company. The line segments run (1) between mileposts V 382.0 at Maben, W. Va., and V 435.0 at DB (Deepwater Bridge), W. Va.; (2) between milepost RR 7.0 at Refugee, Ohio, and milepost RR 116.5 at Hobson Yard, Ohio; (3) between milepost WV 125.6 at Conco, Ohio and milepost WV 253.4 at Cornelia, W. Va.; (4) between milepost VC 0.0 at Vaco Junction, W. Va., and milepost VC 0.84 at Deepwater, W. Va. (5) between Hitop RT at milepost TP 0.0 at Charleston, W. Va., and the end of the track at milepost TP 1.0; (6) between Jones IT at milepost JT 0.0 at Jones, W. Va., and the end of the track at milepost JT 1.3; (7) between milepost VG 0.0 at Virwest, W. Va., and milepost VG 12.1 at Bolt, W. Va., (8) between milepost MY 0.0 at Milam, W. Va., and the end of the track at MY 1.0l; and (9) between milepost PE 0.0 at Putt, W. Va., and milepost PE 2.3 at Putt End Branch, W. Va.

The transaction may be consummated on or after July 31, 2016, the effective date of the exemption, 30 days after the supplemental notice of exemption was filed.

Watco currently controls, indirectly, 33 Class III rail carriers and one Class II rail carrier, collectively operating in 23 states. For a complete list of these rail carriers, and the states in which they operate, see Watco's notice of exemption filed on July 1, 2016. The notice is available on the Board's Web site at *WWW.STB.DOT.GOV.*

Watco represents that: (1) The rail lines to be operated by KNWA do not connect with any other railroads operated by the carrier in the Watco's corporate family; (2) the continuance in control is not part of a series of anticipated transactions that would connect the rail lines to be operated by KNWA with any other railroad in applicant's corporate family; and (3) the transaction does not involve a Class I rail carrier. Therefore, the transaction is exempt from the prior approval requirements of 49 U.S.C. 11323. *See* 49 CFR 1180.2(d)(2).

Under 49 U.S.C. 10502(g), the Board may not use its exemption authority to relieve a rail carrier of its statutory obligation to protect the interests of its employees. Section 11326(c), however, does not provide for labor protection for transactions under 11324 and 11325 that involve only Class III rail carriers. Accordingly, the Board may not impose labor protective conditions here, because all of the carriers involved are Class III carriers.

If the notice contains false or misleading information, the exemption is void ab initio. Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the effectiveness of the exemption. Stay petitions must be filed no later than July 22, 2016 (at least seven days before the exemption becomes effective).

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[1] The notice of exemption was initially filed on June 28, 2016. After representative consultation with the Board, the filing was resubmitted on July 1, 2016, and therefore that is the official filing date and the basis for all dates in this notice.

An original and 10 copies of all pleadings, referring to Docket No. FD 36029, must be filed with the Surface Transportation Board, 395 E Street SW., Washington, DC 20423–0001. In addition, one copy of each pleading must be served on Robert A. Wimbish, Fletcher & Sippel LLC, 29 N. Wacker Drive, Suite 920, Chicago, IL 60606, and Karl Morell, Karl Morell & Associates, Suite 225, 655 Fifteenth St. NW., Washington, DC 20005.

Board decisions and notices are available on our Web site at *WWW.STB.DOT.GOV.*

Decided: July 12, 2016.

By the Board, Rachel D. Campbell, Director, Office of Proceedings.

Tia Delano,

Clearance Clerk.

[FR Doc. 2016–16795 Filed 7–14–16; 8:45 am]

BILLING CODE 4915–01–P

SURFACE TRANSPORTATION BOARD

[Docket No. FD 36045]

Paul Didelius—Continuance in Control Exemption—CWW, LLC

Paul Didelius (Didelius), an individual and noncarrier,[1] has filed a verified notice of exemption pursuant to 49 CFR 1180.2(d)(2) to continue in control of CWW, LLC (CWW), upon CWW's becoming a Class III rail carrier.

This transaction is related to a concurrently filed verified notice of exemption in *CWW, LLC—Lease & Operation Exemption—Port of Columbia, Wash.,* Docket No. FD 36044, wherein CWW seeks Board approval under 49 CFR 1150.31 to lease from the Port of Columbia, Wash., and to operate, approximately 37.1 miles of rail line, referred to as the Dayton Line, between milepost 33.0 near Walla Walla, Wash., and milepost 70.1 at Dayton, Wash.

The transaction may be consummated on or after July 30, 2016, the effective date of the exemption (30 days after the verified notice of exemption was filed).

Didelius represents that: (1) The rail properties that will be operated and controlled by Didelius, namely LRY, YCR, CCET, WRL, and CWW, do not physically connect; (2) there are no plans to acquire additional rail lines for the purpose of making a connection; and (3) each of the carriers involved in the continuance in control transaction is a Class III carrier. Therefore, the transaction is exempt from the prior approval requirements of 49 U.S.C. 11323. *See* 49 CFR 1180.2(d)(2).

Under 49 U.S.C. 10502(g), the Board may not use its exemption authority to relieve a rail carrier of its statutory obligation to protect the interests of its employees. Section 11326(c), however, does not provide for labor protection for transactions under §§ 11324 and 11325 that involve only Class III rail carriers. Accordingly, the Board may not impose labor protective conditions here, because all of the carriers involved are Class III carriers.

If the verified notice contains false or misleading information, the exemption is void ab initio. Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the effectiveness of the exemption. Petitions for stay must be filed no later than June 22, 2016 (at least seven days before the exemption becomes effective).

An original and 10 copies of all pleadings, referring to Docket No. FD 36045, must be filed with the Surface Transportation Board, 395 E Street SW., Washington, DC 20423–0001. In addition, one copy of each pleading must be served on James H.M. Savage, 22 Rockingham Court, Germantown, MD 20874.

Board decisions and notices are available on our Web site at *www.stb.dot.gov.*

Decided: July 12, 2016.

By the Board, Rachel D. Campbell, Director, Office of Proceedings.

Kenyatta Clay,

Clearance Clerk.

[FR Doc. 2016–16782 Filed 7–14–16; 8:45 am]

BILLING CODE 4915–01–P

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[1] Didelius currently owns 100% of LRY, LLC d/b/a Lake Railway (LRY), a Class III carrier that leases and operates rail lines owned by Union Pacific Railroad Company in California and Oregon; 49% of YCR Corporation (YCR), a Class III rail carrier established for the purpose of leasing and operating a line of railroad owned by Yakima County, Wash.; 100% of CCET, LLC (CCET), a Class III short line rail carrier organized for the purpose of leasing and operating a rail line owned by Norfolk Southern Railway Company in Ohio; and 100% of WRL, LLC (WRL), a Class III carrier that leases and operates a rail line owned by Port of Royal Slope, a Washington state municipal corporation, in Washington.

SURFACE TRANSPORTATION BOARD

[Docket No. AB 290 (Sub-No. 387X)]

Chesapeake Western Railway—Discontinuance of Service Exemption—in Rockingham and Shenandoah Counties, VA

Chesapeake Western Railway (CW), a wholly owned subsidiary of Norfolk Southern Railway Company, filed a verified notice of exemption under 49 CFR part 1152 subpart F—*Exempt Abandonments and Discontinuances of Service* to discontinue service over an approximately 15.1-mile rail line, between milepost CW 84.4 at Mt. Jackson, VA, and milepost CW 99.5 at Broadway, VA, in Rockingham and Shenandoah Counties, VA (the Line). The Line traverses United States Postal Service Zip Codes 22842, 22844, 22847, 22853, and 22815.

CW has certified that: (1) No local traffic has moved over the Line for at least two years; (2) no overhead traffic has moved over the Line for at least two years, and if there were any overhead traffic, it could be rerouted over other lines; (3) no formal complaint filed by a user of rail service on the Line (or by a state or local government entity acting on behalf of such user) regarding cessation of service over the Line either is pending before the Surface Transportation Board or any U.S. District Court or has been decided in favor of a complainant within the two-year period; and (4) the requirements at 49 CFR 1105.12 (newspaper publication), and 49 CFR 1152.50(d)(1) (notice to governmental agencies) have been met.

As a condition to this exemption, any employee adversely affected by the discontinuance shall be protected under *Oregon Short Line Railroad—Abandonment Portion Goshen Branch Between Firth & Ammon, in Bingham & Bonneville Counties, Idaho,* 360 I.C.C. 91 (1979). To address whether this condition adequately protects affected employees, a petition for partial revocation under 49 U.S.C. 10502(d) must be filed.

Provided no formal expression of intent to file an offer of financial assistance (OFA) to subsidize continued rail service has been received, this exemption will become effective on August 16, 2016 (50 days after the filing of the exemption), unless stayed pending reconsideration. Petitions to stay that do not involve environmental issues and formal expressions of intent to file an OFA to subsidize continued rail service under 49 CFR 1152.27(c)(2)[1] must be filed by July 25, 2016.[2] Petitions to reopen must be filed by August 4, 2016, with the Surface Transportation Board, 395 E Street SW., Washington, DC 20423–0001.

A copy of any petition filed with the Board should be sent to CW's representative: William A. Mullins, 2401 Pennsylvania Ave. NW., Suite 300, Washington, DC 20037.

If the verified notice contains false or misleading information, the exemption is void ab initio.

Board decisions and notices are available on our Web site at *WWW.STB.DOT.GOV.*

Decided: July 12, 2016.

By the Board, Rachel D. Campbell, Director, Office of Proceedings.

Raina S. Contee,

Clearance Clerk.

[FR Doc. 2016–16774 Filed 7–14–16; 8:45 am]

BILLING CODE 4915–01–P

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[1] Each OFA must be accompanied by the filing fee, which is currently set at $1,600. *See* 49 CFR 1002.2(f)(25).

[2] Because CW is seeking to discontinue service, not to abandon the Line, trail use/rail banking and public use conditions are not appropriate. Because there will be environmental review during abandonment, this discontinuance does not require an environmental review.

SURFACE TRANSPORTATION BOARD

[Docket No. FD 36044]

CWW, LLC—Lease and Operation Exemption—Port of Columbia, Wash.

CWW, LLC (CWW), a noncarrier, has filed a verified notice of exemption under 49 CFR 1150.31 to lease from the Port of Columbia, Wash. and to operate, approximately 37.1 miles of rail line, referred to as the Dayton Line, between milepost 33.0 near Walla Walla, Wash. and milepost 70.1 at Dayton, Wash., pursuant to an executed lease and operating agreement.

This transaction is related to a concurrently filed verified notice of exemption in *Paul Didelius—Continuance in Control Exemption—CWW, LLC,* Docket No. FD 36045, in which Paul Didelius seeks Board approval to continue in control of CWW under 49 CFR 1180.2(d)(2), upon CWW's becoming a Class III rail carrier.

CWW certifies that the projected annual revenues as a result of this transaction do not exceed those that would qualify it as a Class III rail carrier and states the projected annual revenues of CWW shall not exceed $5 million dollars.[1] CWW states that it expects to execute an agreement to interchange with Palouse River & Coulee City Railroad, LLC imposing no interchange commitments.

The transaction may be consummated on August 5, 2016, the effective date of the exemption (30 days after the verified notice of exemption was filed).[2] If the verified notice contains false or misleading information, the exemption is void ab initio. Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the effectiveness of the exemption. Petitions to stay must be filed by July 29, 2016 (at least seven days prior to the date the exemption becomes effective).

An original and 10 copies of all pleadings, referring to Docket No. FD 36044 must be filed with the Surface Transportation Board, 395 E Street SW., Washington, DC 20423–0001. In addition, a copy of each pleading must be served on applicant's representative, James H.M. Savage, 22 Rockingham Court, Germantown, MD 20874.

According to CWW, this action is categorically excluded from environmental review under 49 CFR 1105.6(c).

Board decisions and notices are available on our Web site at *WWW.STB.DOT.GOV.*

Decided: July 12, 2016.

By the Board, Rachel D. Campbell, Director, Office of Proceedings.

Kenyatta Clay,

Clearance Clerk.

[FR Doc. 2016–16781 Filed 7–14–16; 8:45 am]

BILLING CODE 4915–01–P

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[1] By letter filed July 6, 2016, CWW supplemented its notice of exemption with a statement that the projected annual revenues of CWW shall not exceed $5 million dollars.

[2] Because, as noted, CWW supplemented its verified notice on July 6, 2016, that date is considered the filing date of the verified notice.

SURFACE TRANSPORTATION BOARD

[Docket No. FD 36028]

Kanawha River Railroad, LLC—Lease Exemption Containing Interchange Commitment—Norfolk Southern Railway Company

Kanawha River Railroad, LLC (KNWA), a noncarrier, has filed a verified notice of exemption under 49 CFR 1150.41 to lease and operate nine rail segments totaling 308.85 miles from Norfolk Southern Railway Company (NSR). These line segments run (1) between mileposts V 382.0 at Maben, W. Va., and V 435.0 at DB (Deepwater Bridge), W. Va.; (2) between milepost RR 7.0 at Refugee, Ohio, and milepost RR 116.5 at Hobson Yard, Ohio; (3) between milepost WV 125.6 at Conco, Ohio and milepost WV 253.4 at Cornelia, W. Va.; (4) between milepost VC 0.0 at Vaco Junction, W. Va., and milepost VC 0.84 at Deepwater W. Va.; (5) between Hitop RT at milepost TP 0.0 at Charleston, W. Va., and the end of the track at milepost TP 1.0; (6) between Jones IT at milepost JT 0.0 at Jones, W. Va., and the end of the track at milepost JT 1.3; (7) between milepost VG 0.0 at Virwest, W. Va., and milepost VG 12.1 at Bolt, W. Va., (8) between milepost MY 0.0 at Milam, W. Va., and the end of the track at MY 1.01; and (9) between milepost PE 0.0 at Putt, W. Va., and milepost PE 2.3 at Putt End Branch, W. Va.[1]

This transaction is related to a concurrently filed verified notice of exemption in *Watco Holdings, Inc.—Continuance in Control Exemption—Kanawha River Railroad LLC,* Docket No. FD 36029, wherein Watco Holdings, Inc. seeks Board authority to continue in control of KNWA upon KNWA's becoming a Class III rail carrier.

KNWA plans to lease and increase operations on the subject rail lines in Ohio and West Virginia (189 miles of the subject lines are in active service; the remainder of the track is idled or has been taken out of service by NSR).[2] KNWA intends to return the entire main line component of the rail lines to daily operation. NSR suspended operations on part of the rail lines in Ohio in early 2016 due to declining rail traffic volumes, and rerouted traffic on other routes.

KNWA has certified that its projected annual revenues that will result from the proposed transaction will not result in KNWA becoming a Class II or Class I rail carrier. KNWA has further certified that its projected annual rail freight revenues, including the lines to be operated pursuant to this notice, will exceed $5 million. Accordingly, as required by 49 CFR 1150.42(e), KNWA has certified that on May 18 and 19,

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[1] The notice of exemption was initially filed on June 28, 2016, but was resubmitted with corrections on July 1, 2016. Therefore July 1, 2016, is the official filing date and the basis for all dates in this notice.

[2] KNWA has filed the lease agreement under seal pursuant to 49 CFR 1150.43(h)(1)(ii). On July 7, 2016, Dow Chemical Company (Dow) filed a motion for access to the confidential lease documents, pursuant to 49 CFR 1150.43(h)(2), and a motion for protective order. On July 8, 2016, M&G Polymers USA, LLC (M&G) filed similar motions. Both Dow and M&G stated that KNWA had agreed to grant such access once a protective order was in place. On July 8, 2016, the Board granted M&G's motion for protective order and motion for access to confidential documents. On July 11, 2016, the Board granted Dow's motion for access to confidential documents.

2016, a copy of the verified notice was posted at the workplaces of the employees on the line and served on the national offices of all labor unions with employees on the line.

The transaction may be consummated on or after July 31, 2016, the effective date of the exemption (30 days after the supplemental notice of exemption was filed).

If the verified notice contains false or misleading information, the exemption is void ab initio. Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the effectiveness of the exemption. Petitions for stay must be filed no later than July 22, 2016 (at least 7 days before the exemption becomes effective).

An original and 10 copies of all pleadings, referring to Docket No. FD 36028, must be filed with the Surface Transportation Board, 395 E Street SW., Washington, DC 20423–0001. In addition, a copy of each pleading must be served on Robert A. Wimbish, Fletcher & Sippel LLC, 29 N. Wacker Drive, Suite 920, Chicago, IL 60606, and Karl Morell, Karl Morell & Associates, Suite 225, 655 Fifteenth St. NW., Washington, DC 20005.

According to KNWA, this action is categorically excluded from environmental review under 49 CFR 1105.6(c).

Board decisions and notices are available on our Web site at *WWW.STB.DOT.GOV.*

Decided: July 12, 2016.

By the Board, Rachel D. Campbell, Director, Office of Proceedings.

Tia Delano,

Clearance Clerk.

[FR Doc. 2016–16796 Filed 7–14–16; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Opportunity for Public Comment on Non-Rulemaking Action To Change Land Use From Aeronautical to Non-Aeronautical at Jackson-Medgar Wiley Evers International Airport, Jackson, Mississippi

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice.

SUMMARY: Under the provisions of title 49, U.S.C. 47153(c), notice is being given that the FAA is considering a request from the Jackson Municipal Airport Authority to waive the requirement that a 130 acre parcel of surplus property, located on Jackson-Medgar Wiley Evers International Airport, be used for aeronautical purposes.

DATES: Comments must be received on or before August 15, 2016.

ADDRESSES: Comments on this notice may be mailed or delivered in triplicate to the FAA at the following address: Jackson Airports District Office, Attn: Jeff Orr, Program Manager, 100 West Cross Street, Suite B, Jackson, MS 39208–2307.

In addition, one copy of any comments submitted to the FAA must be mailed or delivered to Mr. Carl Newman, Chief Executive Officer, Jackson Municipal Airport Authority at the following address: P.O. Box 98109, Jackson, MS 39298–8109.

FOR FURTHER INFORMATION CONTACT: Jeff Orr, Program Manager, Jackson Airports District Office, 100 West Cross Street, Suite B, Jackson, MS 39208–2307, (601) 664–9885. The application may be reviewed in person at this same location.

SUPPLEMENTARY INFORMATION: If the proposal is approved, the airport layout plan will be updated to reflect the change in the land use on 130 acres from aeronautical to non-aeronautical. The property will then be leased for Commercial Development. The location of the land relative to existing or anticipated aircraft noise contours greater than 65 DNL are not considered to be an issue. The proceeds from the lease of this property will be used for airport purposes. The proposed use of this property is compatible with airport operations.

Any person may inspect the request in person at the FAA office listed above under **FOR FURTHER INFORMATION CONTACT**.

In addition, any person may, upon request, inspect the request, notice and other documents germane to the request in person at the Jackson-Medgar Wiley Evers International Airport.

Issued in Jackson, Mississippi on July 7, 2016.

William J. Schuller,

Acting Manager, Jackson Airports District Office, Southern Region.

[FR Doc. 2016–16815 Filed 7–14–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket Number FRA–2016–0002–N–14]

Proposed Agency Information Collection Activities; Comment Request

AGENCY: Federal Railroad Administration (FRA), Department of Transportation (DOT).

ACTION: Notice and request for comments.

SUMMARY: Under the Paperwork Reduction Act of 1995 (PRA), this notice announces FRA is forwarding the renewal of the information collection requirements (ICR) abstracted below to the Office of Management and Budget (OMB) for review and comment. The ICR describes the nature of the information collection and its expected burden. On February 25, 2016, OMB approved Form FRA F 1680.167 for 180 days under emergency clearance procedures. FRA seeks regular clearance of this form for the maximum period (3 years) to comply with Fixing America's Surface Transportation Act (FAST Act) requirements. The **Federal Register** notice with a 60-day comment period soliciting comments on the following collection of information was published on March 24, 2016.

DATES: Comments must be submitted on or before August 15, 2016.

FOR FURTHER INFORMATION CONTACT: Mr. Robert Brogan, Information Collection Clearance Officer, Office of Railroad Safety, Safety Regulatory Analysis Division, RRS–21, Federal Railroad Administration, 1200 New Jersey Avenue SE., Mail Stop 25, Washington, DC 20590, (202) 493–6292, or Ms. Kimberly Toone, Information Collection Clearance Officer, Office of Administration, Office of Information Technology, RAD–20, Federal Railroad Administration, 1200 New Jersey Avenue SE., Mail Stop 35, Washington, DC 20590, (202) 493–6132. These telephone numbers are not toll-free.

SUPPLEMENTARY INFORMATION: The PRA, 44 U.S.C. 3501–3520, and its implementing regulations, Title 5 Code of Federal Regulations (CFR) part 1320, require Federal agencies to issue two notices seeking public comment on information collection activities before OMB may approve paperwork packages. *See* 44 U.S.C. 3506, 3507; 5 CFR 1320.5, 1320.8(d)(1), and 1320.12. On March 24, 2016, FRA published a 60-day notice in the **Federal Register** soliciting comment on ICRs for which the agency is seeking OMB approval. *See* 81 FR 15781. FRA received no comment in response to that notice. However, FRA did receive a comment from the Association of American Railroads (AAR) on February 26, 2016, in response to FRA's February 19, 2016, **Federal Register** notice (*see* 81 FR 8588) requesting Emergency Clearance from OMB for the information collection activities described below. FRA is responding to that comment now.

AAR commented that FRA expects the railroads will provide information on (i) the type of bridge (superstructure) and (ii) type of structure (substructure). AAR states "there are different interpretations of these terms that fulfill the requirements of the FAST Act, including that the 'type of bridge' means its material composition and 'type of structure' means its superstructure." FRA finds that AAR's comment is reasonable and FRA will interpret "type of bridge" to mean its material composition and "type of structure" to mean its superstructure. As examples, the combination of type of bridge and structure could yield descriptions such as: Stone Arch, Steel Through Plate Girder on Concrete Abutments, Steel Multi-beams on Stone Abutments and Steel Column Bents, and Concrete Box Beams on Reinforced Concrete Piers and Abutments.

Additionally, AAR commented that FRA will require railroads to respond to the inspection report request within 30 days. AAR explains that "as the FAST Act does not require a railroad to respond to a request in a set time period, FRA should allow a railroad additional time to respond to a request for multiple public bridge inspection reports." FRA believes that 30 days is sufficient time for railroads to respond. However, FRA will consider longer periods on a case-by-case basis if there are extenuating circumstances.

Before OMB decides whether to approve these proposed collections of information, it must provide 30 days for public comment. *See* 44 U.S.C. 3507(b), 5 CFR 1320.12(d). Federal law requires OMB to approve or disapprove paperwork packages between 30 and 60 days after the 30-day notice is published. *See* 44 U.S.C. 3507(b)–(c); 5 CFR 1320.12(d); *see also* 60 FR 44978, 44983, August 29, 1995. OMB believes that the 30-day notice informs the regulated community to file relevant comments and affords the agency adequate time to digest public comments before it renders a decision. *See* 60 FR 44983, August 29, 1995. Therefore, respondents should submit their respective comments to OMB within 30 days of publication to best ensure having their full effect. *See* 5 CFR 1320.12(c); *see also* 60 FR 44983, August 29, 1995.

The summary below describes the ICR and its expected burden. The renewal request is being submitted for OMB clearance as the PRA requires.

Title: Bridge Safety Standards.

OMB Control Number: 2130–0586.

Abstract: On December 4, 2015, U.S. President Barack Obama signed the FAST Act into law (Pub. L. 114–94). Section 11405, Bridge Inspection Reports, provides a means for a State or a political subdivision of a State to obtain a public version of a bridge inspection report generated by a railroad for a bridge located within its respective jurisdiction. While the FAST Act specifies that requests for such reports must be filed with the Secretary of Transportation, the responsibility for fulfilling these requests is delegated to FRA. *See* 49 CFR 1.89.

FRA previously revised its currently approved information collection to account for the additional burden States and political subdivisions of States will incur for requesting a public version of a bridge inspection report generated by a railroad for a bridge located within its respective jurisdiction. FRA developed a new form titled "Bridge Inspection Report Public Version Request Form" to facilitate such State and their political subdivisions' requests. Additionally, FRA revised its currently approved information collection to account for the additional burden railroads will incur to provide the public version of a bridge inspection report upon FRA request.

As background, on July 15, 2010, FRA published its Bridge Safety Standards Final Rule. *See* 75 FR 41281. The final rule on bridge safety standards normalized and established Federal requirements for railroad bridges. The final rule establishes minimum requirements to assure the structural integrity of railroad bridges and to protect the safe operation of trains over those bridges. The final rule requires railroads/track owners to implement bridge management programs to prevent the deterioration of railroad bridges and to reduce the risk of human casualties, environmental damage, and disruption to the Nation's transportation system that would result from a catastrophic bridge failure. Bridge management programs must include annual inspection of bridges as well as special inspections, which must be conducted if natural or accidental events cause conditions that warrant such inspections. Lastly, the final rule requires railroads/track owners to audit bridge management programs and bridge inspections and to keep records mandated under 49 CFR part 237, Bridge Safety Standards. This final rule culminated FRA's efforts to develop and promulgate bridge safety regulations and fulfilled the Rail Safety Improvement Act of 2008 (Pub. L. 110–432, Division A) mandate.

FRA uses the information collected to ensure railroads/track owners meet Federal standards for bridge safety and comply with all the requirements of this regulation. In particular, FRA uses the collection of information to confirm that railroads/track owners adopt and implement bridge management programs to properly inspect, maintain, modify, and repair all bridges that carry trains over them and for which they are responsible. Railroads/track owners must conduct annual inspections of railroad bridges. Further, railroads/track owners must incorporate provisions for internal audits into their bridge management program and must conduct internal audits of bridge inspection reports. Railroads/track owners use the internal audit information to verify the inspection provisions of the bridge management program are being followed and to continually evaluate the effectiveness of their bridge management program and bridge inspection activities. FRA uses this information to ensure railroads/track owners implement a safe and effective bridge management program and bridge inspection regime.

Type of Request: Extension without change of a currently approved information collection under regular clearance procedures.

Affected Public: Businesses (Railroads).

Form(s): Form FRA F 6180.167.

Total Annual Estimated Responses for New FAST Act Requirements: 150.

Total Annual Estimated Responses for Entire Information Collection: 49,271.

Total Annual Estimated Burden for New FAST Act Requirements: 81 hours.

Total Annual Estimated Burden for Entire Information Collection: 224,689 hours.

Addressee: Send comments regarding these information collections to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 Seventeenth Street NW., Washington, DC 20503, Attention: FRA Desk Officer. Comments may also be sent via email to OMB at the following address: *oira_submissions@omb.eop.gov.*

Comments are invited on the following: Whether the proposed collections of information are necessary for the proper performance of the functions of the Department, including (i) whether the information will have practical utility; (ii) the accuracy of the

Department's estimates of the burden of the proposed information collections; (iii) ways to enhance the quality, utility, and clarity of the information to be collected; and (iv) ways to minimize the burden of the collections of information on respondents, including the use of automated collection techniques or other forms of information technology.

A comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication of this notice in the **Federal Register**.

Authority: 44 U.S.C. 3501–3520.

Issued in Washington, DC, on July 12, 2016.

Corey Hill,

Executive Director.

[FR Doc. 2016–16771 Filed 7–14–16; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket Number FRA–2016–0055]

Petition for Waiver of Compliance

In accordance with part 211 of title 49 Code of Federal Regulations (CFR), this provides the public notice that by a document dated April 1, 2016, Union Pacific Railroad (UP) has petitioned the Federal Railroad Administration (FRA) for a waiver of compliance from certain provisions of the Federal railroad safety regulations contained at 49 CFR part 229—Railroad Locomotive Safety Standards. FRA assigned the petition Docket Number FRA–2016–0055.

Specifically, UP is seeking an exemption, until October 1, 2018, from the requirements of 49 CFR 229.135(b)(5) and (6), which require the use of a crash-hardened memory module as specified in Appendix D to part 229.

Title 49 CFR 229.135(b)(5) and (6) allow for a phased-in approach for upgrading the memory modules. Railroads are not required to replace functioning modules installed prior to the availability of crash-worthy modules (CHM) until the locomotives are remanufactured. Similarly, outside of the remanufacturing process, railroads have been permitted to use replacement modules that do not meet Appendix D requirements if the modules were originally manufactured prior to 2010.

As background, in September 2011, UP submitted a Request for Proposal to multiple vendors to procure a Locomotive Data Acquisition Recording System (LDARS) to meet FRA's requirement to calibrate/synchronize the event recorder and Positive Train Control (PTC) data feeds into a CHM. UP awarded the contract in March 2012 for the development of a crash-worthy LDARS in accordance with the Federal requirements. These modules would capture and synchronize existing FRA-required event-recorder data and FRA-required PTC information. In addition, UP specified LDARS be capable of recording event-recorder data feeds from a variety of locomotive control systems and data collection devices and integrating with currently installed event recorders. The vendor promised a scheduled delivery date of April 2014. However, UP did not receive a production-capable LDARS unit until September 2014. UP purchased and had planned to deploy 1,500 LDARS systems starting in the fourth quarter of 2014 but due to technology issues with LDARS, the purchased units had to be shipped back to the vendor for rework, and subsequent production of LDARS units stopped. The vendor has certified LDARS as being U.S. Department of Transportation crashworthy.

As a result of these unanticipated issues, UP experienced significant delay in accepting and installing LDARS products. There were several issues contributing to the delay, specifically, issues with the memory module firmware and LSI interface, resulting in gaps in the recorded data and gaps in the video and audio feed. These issues have required UP to "shop" the locomotives for a third time for installation of PTC onboard components.

Of the 5,656 planned PTC locomotives UP intends to replace, roughly 1,100 event recorders are not capable of integration with LDARS. There are 2,000 crash-hardened integrated data recorders that will be replaced with LDARS to meet FRA calibration requirements.

UP has more than 2,500 locomotives that have all of the equipment installed for PTC with the exception of LDARS. After UP qualifies LDARS, installation will be scheduled on the 90-day periodic maintenance inspection cycle for the 2,500 locomotives which are PTC ready, except for LDARS that are in the fleet today. The balance will be installed as UP continues to equip through September 2018, roughly 1,100 locomotives per year.

A copy of the petition, as well as any written communications concerning the petition, is available for review online at *www.regulations.gov* and in person at the U.S. Department of Transportation's (DOT) Docket Operations Facility, 1200 New Jersey Avenue SE., W12–140, Washington, DC 20590. The Docket Operations Facility is open from 9 a.m. to 5 p.m., Monday through Friday, except Federal Holidays.

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a hearing. If any interested party desires an opportunity for oral comment, they should notify FRA, in writing, before the end of the comment period and specify the basis for their request.

All communications concerning these proceedings should identify the appropriate docket number and may be submitted by any of the following methods:

- *Web site: http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* Docket Operations Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE., W12–140, Washington, DC 20590.
- *Hand Delivery:* 1200 New Jersey Avenue SE., Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.

Communications received by August 29, 2016 will be considered by FRA before final action is taken. Comments received after that date will be considered as far as practicable.

Anyone is able to search the electronic form of any written communications and comments received into any of our dockets by the name of the individual submitting the comment (or signing the document, if submitted on behalf of an association, business, labor union, etc.). In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its processes. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy.* See also *http://www.regulations.gov/#!privacyNotice* for the privacy notice of *regulations.gov.*

Robert C. Lauby,

Associate Administrator for Railroad Safety, Chief Safety Officer.

[FR Doc. 2016–16705 Filed 7–14–16; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. USCG–2015–0472]

Deepwater Port License Application: Delfin LNG LLC, Delfin LNG Deepwater Port

AGENCY: Maritime Administration, Department of Transportation

ACTION: Notice of availability; notice of public meeting; request for comments.

SUMMARY: The Maritime Administration (MARAD), in cooperation with the U.S. Coast Guard (USCG) and the Federal Energy Regulatory Commission (FERC), announces the availability of the Draft Environmental Impact Statement (DEIS) for the Delfin LNG deepwater port license application for the exportation of natural gas. Delfin LNG, LLC (Delfin LNG), is the applicant.

A Notice of Application that summarized the original Delfin LNG license application was published in the **Federal Register** on July 16, 2015 (80 FR 42162). A Notice of Intent to Prepare an Environmental Impact Statement (EIS) and Notice of Public Meetings was published in the **Federal Register** on July 29, 2015 (80 FR 45270). A Notice of Receipt of Amended Application was published in the **Federal Register** on December 24, 2015 (80 FR 80455). This Notice of Availability (NOA) incorporates the aforementioned Notices by reference.

The proposed Delfin LNG deepwater port would be located in Federal waters within the Outer Continental Shelf (OCS) approximately 37.4 to 40.8 nautical miles off the coast of Cameron Parish, Louisiana.

The proposed Delfin LNG deepwater port incorporates onshore components, which are subject to FERC jurisdiction. These facilities are described in the section of this Notice titled "FERC Application."

Publication of this notice begins a 45-day comment period, requests public participation in the environmental impact review process, provides information on how to participate in the process and announces informational open houses and public meetings in Cameron, Louisiana and Beaumont, Texas.

DATES: The Maritime Administration will hold two public meetings in connection with the license application DEIS. The first public meeting will be held in Cameron, Louisiana, on August 9, 2016, from 6 p.m. to 8 p.m. The second public meeting will be held in Beaumont, Texas, on August 10, 2016, from 6 p.m. to 8 p.m. Each public meeting will be preceded by an open house from 4:30 p.m. to 5:30 p.m. The public meeting may end later than the stated time, depending on the number of persons who wish to make a comment on the record. Additionally, material you submit in response to the request for comments must reach *www.regulations.gov* by close of business August 29, 2016, or 45 days after the date of publication of this NOA in the **Federal Register**, whichever is later.

ADDRESSES: The open house and public meeting in Cameron, Louisiana will be held at the Johnson Bayou Community Center, 5556 Gulf Beach Highway, Cameron, LA, 70631; telephone: 337–569–2454. Free parking is available at the Community Center. The open house and public meeting in Beaumont, Texas will be held at the Holiday Inn Beaumont Plaza, 3950 Walden Road, Beaumont, Texas 77705; telephone: 409–842–5995. Free parking is available at the Holiday Inn Beaumont Plaza.

The license application, comments, supporting information and the DEIS are available for viewing at the *Regulations.gov* Web site: *http://www.regulations.gov* under docket number USCG–2015–0472. The Final EIS (FEIS), when published, will be announced and available at this site as well.

We encourage you to submit comments electronically through the Federal eRulemaking Portal at *http://www.regulations.gov*. If you submit your comments electronically, it is not necessary to also submit a hard copy. If you cannot submit material using *http://www.regulations.gov,* please contact either Mr. Roddy Bachman, USCG or Ms. Yvette M. Fields, MARAD, as listed in the following **FOR FURTHER INFORMATION CONTACT** section of this document. This section provides alternate instructions for submitting written comments. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted. Anonymous comments will be accepted. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information you have provided.

FOR FURTHER INFORMATION CONTACT: Mr. Roddy Bachman, USCG, telephone: 202–372–1451, email: *Roddy.C.Bachman@uscg.mil;* or Ms. Yvette M. Fields, Director, Office of Deepwater Ports and Offshore Activities, MARAD, telephone: 202–366–0926, email: *Yvette.Fields@dot.gov.*

SUPPLEMENTARY INFORMATION:

Request for Comments

We request public comments or other relevant information related to the DEIS for the proposed Delfin LNG deepwater port. These comments will inform our preparation of the FEIS. We encourage attendance at the open houses and public meetings; however, you may submit comments electronically. It is preferred that comments be submitted electronically. Regardless of the method you use to submitting comments or material, all submissions will be posted, without change, to the Federal Docket Operations Facility Web site (*http://www.regulations.gov*), and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to read the Privacy and Use Notice that is available on the *www.regulations.gov* Web site, and the Department of Transportation (DOT) Privacy Act Notice that appeared in the **Federal Register** on April 11, 2000 (65 FR 19477), see PRIVACY ACT. You may view docket submissions at the DOT Docket Operations Facility or electronically at the *www.reguations.gov* Web site.

Public Meeting and Open House

You are invited to learn about the proposed Delfin LNG deepwater port at either of the informational open houses and to comment on the proposed action and the environmental impact analysis contained in the DEIS. Speakers may register upon arrival and will be recognized in the following order: Elected officials, public agency representatives, then individuals or groups in the order in which they registered. In order to accommodate all speakers, speaker time may be limited, meeting hours may be extended, or both. Speakers' transcribed remarks will be included in the public docket. You may also submit written material for inclusion in the public docket. Written material must include the author's name. We ask attendees to respect the meeting procedures in order to ensure a constructive information-gathering session. Please do not bring signs or banners inside the meeting venue. The presiding officer will use his/her discretion to conduct the meeting in an orderly manner.

Public meeting locations are wheelchair accessible; however, attendees who require special assistance such as sign language interpretation or other reasonable accommodation, please notify the USCG (see **FOR FURTHER INFORMATION CONTACT**) at least five (5) business days in advance. Please include contact information as well as information about specific needs.

Background

On May 8, 2015, as supplemented on June 19, 2015, MARAD and USCG received a license application from Delfin LNG for all Federal authorizations required for a license to own, construct and operate a deepwater port for the export of natural gas. The proposed deepwater port would be located in Federal waters approximately 37.4 to 40.8 nautical miles off the coast of Cameron Parish, Louisiana. Louisiana and Texas were designated as Adjacent Coastal States (ACS) for the Delfin LNG license application.

The Federal agencies involved held two public scoping meetings in connection with the original Delfin LNG license application. The first public scoping meeting was held in Lake Charles, Louisiana on August 18, 2015; the second public scoping meeting was held in Beaumont, Texas on August 19, 2015. Transcripts of the scoping meetings are included in the public docket. After the public scoping meetings concluded, Delfin LNG advised MARAD, the USCG and FERC of its intent to amend the original license application.

In anticipation of the amended license application, MARAD and USCG issued a regulatory "stop-clock" letter to Delfin LNG on September 18, 2015. That letter commenced a regulatory "stop-clock," effective September 18, 2015, which remained in effect until MARAD and USCG received the amended license application and determined it contained sufficient information to continue the Federal review process. On November 19, 2015, Delfin LNG submitted its amended license application to MARAD and USCG.

Working in coordination with participating Federal and State agencies, MARAD commenced processing the amended license application and completed the DEIS. The purpose of the DEIS is to analyze reasonable alternatives to, and the direct, indirect and cumulative environmental impacts of, the proposed action. The DEIS is currently available for public review at the Federal docket Web site: *www.regulations.gov* under docket number USCG–2015–0472.

Summary of the License Application

Delfin LNG is proposing to construct, own, operate and eventually decommission a deepwater port in the Gulf of Mexico to liquefy domestically-sourced natural gas for export. Exports are proposed to both Free Trade Agreement nations and non-Free Trade Agreement nations, in accordance with Department of Energy export license approvals.

The proposed Delfin LNG deepwater port has both onshore and offshore components. As previously described, the proposed Delfin LNG deepwater port would be located in Federal waters within the OCS West Cameron Area, West Addition Protraction Area (Gulf of Mexico) approximately 37.4 to 40.8 nautical miles off the coast of Cameron Parish, Louisiana, in water depths ranging from approximately 64 to 72 feet (19.5 to 21.9 meters). The Delfin LNG deepwater port would consist of four semi-permanently moored Floating Liquefied Natural Gas Vessels (FLNGVs) located as follows: #1 (29°8′13.1″ N./93°2′2.2″ W.), #2 (29°6′13.6″ N./93° 32′42.4″ W.), #3 (29°6′40.7″ N./93°30′10.1″ W.) and #4 (29°4′40.9″ N./93°30′51.8″ W.) located in West Cameron (WC) lease blocks 319, 327, 328 and 334, respectively. The Delfin LNG deepwater port would reuse and repurpose two existing offshore natural gas pipelines; the former U–T Operating System (UTOS) pipeline and the High Island Operating System (HIOS) pipeline. Four new 30-inch diameter pipeline laterals, each approximately 6,400 feet in length, connecting the HIOS pipeline to each of the FLNGVs, would be constructed. In addition, a 700-foot 42-inch diameter new pipeline would be constructed to bypass a platform at WC lease block 167 (WC 167) and connect the UTOS and HIOS pipelines. Feed gas would be supplied through the new pipeline laterals to each of the FLNGVs where it would be super-cooled to produce LNG. The LNG would be stored onboard the FLNGVs and transferred via ship-to-ship transfer to properly certified LNG tankers. Each of the FLNGVs would be semi-permanently moored to four new weathervaning tower yoke mooring systems (TYMS).

The onshore components in Cameron Parish, Louisiana are described specifically in an application submitted to FERC. The onshore components of the Delfin LNG deepwater port will consist of constructing and operating a new natural gas compressor station, gas supply header and a metering station at an existing gas facility. The proposal would require: (1) Reactivation of approximately 1.1 miles of existing 42-inch pipeline, formerly owned by UTOS, which runs from Transcontinental Gas Pipeline Company Station No. 44 (Transco Station 44) to the mean highwater mark along the Cameron Parish Coast; (2) installation of 120,000 horsepower of new compression; (3) construction of 0.25 miles of 42-inch pipeline to connect the former UTOS line to the new meter station; and (4) construction of 0.6 miles of twin 30-inch pipelines between Transco Station 44 and the new compressor station.

Onshore pipeline quality natural gas from the interstate grid would be sent to the existing, but currently idle, 42-inch UTOS pipeline. The gas transported through the UTOS pipeline would then bypass the existing manifold platform located at WC 167 via a newly installed pipeline segment, 700 feet in length, connecting to the existing 42-inch HIOS pipeline.

The bypass of the WC 167 platform would be trenched so that the top of the pipe is a minimum of 3 feet below the seafloor. From the bypass, the feed gas would then be transported further offshore using the HIOS pipeline portion leased by Delfin LNG between WC 167 and High Island A264. The existing UTOS and HIOS pipelines transect OCS Lease Blocks WC 314, 318, 319, 327, and 335, and would transport feed gas from onshore to offshore (one-directional flow). Delfin LNG proposes to install four new lateral pipelines along the HIOS pipeline, starting approximately 16.0 nautical miles south of the WC 167 platform. Each subsea lateral pipeline would be 30 inches in diameter and approximately 6,400 feet in length, extending from the HIOS pipeline to the Delfin LNG deepwater port. The maximum allowable operating pressure of the pipeline system (UTOS, bypass, HIOS and laterals) would be 1,250 pounds per square inch gauge (psig).

The FLNGVs would receive pipeline quality natural gas via the laterals and TYMS where it would be cooled sufficiently to completely condense the gas and produce LNG. The produced LNG would be stored in International Maritime Organization (IMO) type B, prismatic, independent LNG storage tanks aboard each of the FLNGVs. Each vessel would have a total LNG storage capacity of 210,000 cubic meters (m^3).

An offloading mooring system would be provided on each FLNGV to moor an LNG tanker side-by-side for cargo transfer of LNG through loading arms or cryogenic hoses using ship-to-ship transfer procedures. LNG tankers would be moored with pilot and tug assist. The FLNGVs would be equipped with fenders and quick-release hooks to facilitate mooring and unmooring operations. The offloading system would be capable of accommodating standard LNG tankers with nominal cargo capacities up to 170,000 m^3. Delfin LNG estimates that the typical LNG cargo transfer operation would be carried out within 24 hours, including LNG tanker berthing, cargo transfer and sail-away. Approximately 31 LNG tankers are expected to visit each of the four FLNGVs per year for a total of up to 124 cargo transfer operations per year. Each LNG tanker would be assisted by up to three tugs during approach and mooring and up to two tugs while departing the Delfin LNG deepwater port.

The FLNGVs would be self-propelled vessels and have the ability to disconnect from the TYMS and set sail to avoid hurricanes or to facilitate required inspections, maintenance and repairs.

In the nominal design case, based on an estimated availability of 92 percent and allowance for consumption of feed gas during the liquefaction process, each of the four FLNGVs would produce approximately 146 billion standard cubic feet per year (Bscf/y) of gas (approximately 3.0 million metric tonnes per annum [MMtpa]) for export in the form of LNG. Together, the four FLNGVs are designed to have the capability to export 585 Bscf/y of gas (approximately 12.0 MMtpa).

As detailed engineering and equipment specification advances during the design process and operating efficiencies are gained post-commissioning, the liquefaction process could perform better than this nominal design case. It is anticipated that LNG output could improve to as much as 657.5 Bscf/y in the optimized design case (approximately 13.2 MMtpa) which is the amount Delfin LNG is requesting authorization to export.

The proposed Delfin LNG deepwater port would take a modular implementation approach to allow for early market entry and accommodate market shifts. Offshore construction activities are proposed to begin at the end of first quarter of 2018 and would be completed in four stages, with each stage corresponding to the commissioning and operation of an FLNGV. The anticipated commissioning of FLNGV 1 is the third quarter of 2019 with start-up of commercial operation of FLNGV 1 by the end of 2019. It is anticipated that FLNGVs 2 through 4 would be commissioned 12 months apart. Following this schedule and barring unforeseen events, the Delfin deepwater port would be completed and all four FLNGVs would be fully operational by the summer of 2022.

Should a license be issued, the Delfin LNG deepwater port would be designed, fabricated, constructed, commissioned, maintained, inspected and operated in accordance with applicable codes and standards and with USCG oversight as regulated under Title 33, Code of Federal Regulations (CFR), subchapter NN-Deepwater Ports (33 CFR 148, 149 and 150). This includes applicable waterways management and regulated navigations areas, maritime safety and security requirements, risk assessment and compliance with domestic and international laws and regulations for vessels that may call at the port.

FERC Application

On May 8, 2015, Delfin LNG filed its original application with FERC requesting authorizations pursuant to the Natural Gas Act and 18 CFR part 157 for the onshore components of the proposed deepwater port terminal including authorization to use the existing pipeline infrastructure, which includes leasing a segment of pipeline from HIOS extending from the terminus of the UTOS pipeline offshore. On May 20, 2015, FERC issued its *Notice of Application* for the onshore components of Delfin LNG's deepwater port project in Docket No. CP15–490–000. This Notice was published in the **Federal Register** on May 27, 2015 (80 FR 30226). Delfin LNG stated in its application that High Island Offshore System, LLC would submit a separate application with FERC seeking authorization to abandon by lease its facilities to Delfin LNG. FERC, however, advised Delfin LNG that it would not begin processing Delfin LNG's application until such time that MARAD and USCG deemed Delfin LNG's deepwater port license application complete and High Island Offshore System, LLC submitted an abandonment application with FERC. On June 29, 2015, MARAD and USCG accepted the documentation and deemed the original Delfin license application complete.

On November 19, 2015, High Island Offshore System, LLC filed an application (FERC Docket No. CP16–20–000) to abandon certain offshore facilities in the Gulf of Mexico, including its 66-mile-long mainline, an offshore platform and related facilities (''HIOS Repurposed Facilities''). Accordingly, on November 19, 2015, Delfin LNG filed an amended application in FERC Docket No. CP15–490–001 to use the HIOS Repurposed Facilities and to revise the onshore component of its deepwater port project. On December 1, 2015, FERC issued a *Notice of Application* for Delfin LNG's amendment, which was published in the **Federal Register** on December 7, 2015 (80 FR 76003).

The amended FERC application specifically discusses the onshore facility and adjustments to the onshore operations that would involve reactivating approximately 1.1 miles of the existing UTOS pipeline; the addition of four new onshore compressors totaling 120,000 horsepower of new compression; activation of associated metering and regulation facilities; the installation of new supply header pipelines (which would consist of 0.25 miles of new 42-inch-diameter pipeline to connect the former UTOS line to the new meter station); and 0.6 miles of new twin 30-inch-diameter pipelines between Transco Station 44 and the new compressor station site.

Additional information regarding the details of Delfin LNG's original and amended application to FERC is on file and open to public inspection. Project filings may be viewed on the web at *www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits (*i.e.,* CP15–490) in the docket number field to access project information. For assistance, please contact FERC at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Privacy Act

Regardless of the method used for submitting comments or materials, all submissions will be posted, without change, to *www.regulations.gov* and will include any personal information you provide. Therefore, submitting this information to the docket makes it public. You may wish to read the Privacy and Security Notice, as well as the User Notice, that is available on the *www.regulations.gov* Web site. The Privacy Act notice regarding the Federal Docket Management System is available in the March 24, 2005, issue of the **Federal Register** (70 FR 15086).

Authority: 33 U.S.C. 1501 *et seq.*, 49 CFR 1.93(h).

Dated: July 7, 2016.

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2016–16540 Filed 7–14–16; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

Applications of 21 Air, LLC for Certificate Authority

AGENCY: Department of Transportation.

ACTION: Notice of Order to Show Cause (Order 2016–7–5) Dockets DOT–OST–2015–0043 and DOT–OST–2015–0044.

SUMMARY: The Department of Transportation is directing all interested persons to show cause why it should not issue orders finding 21 Air, LLC, fit, willing, and able, and awarding it certificates of public convenience and necessity authorizing it to engage in interstate and foreign charter air transportation of property and mail.

DATES: Persons wishing to file objections should do so no later than July 25, 2016

ADDRESSES: Objections and answers to objections should be filed in Dockets DOT–OST–2015–0043 and DOT–OST–2015–0044 and addressed to the Department of Transportation, Docket Operations, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12–140, Washington, DC and should be served upon the parties listed in Attachment A to the order.

FOR FURTHER INFORMATION CONTACT: Damon D. Walker, Air Carrier Fitness Division, (X–56, Office W86–469), U.S. Department of Transportation, 1200 New Jersey Avenue SE., Washington, DC 20590, (202) 366–9721.

Dated: July 8, 2016.

Jenny T. Rosenberg,

Acting Assistant Secretary for Aviation and International Affairs.

[FR Doc. 2016–16753 Filed 7–14–16; 8:45 am]

BILLING CODE P

DEPARTMENT OF TRANSPORTATION

Office of The Secretary

Application of Rectrix Aviation, Inc. for Commuter Authority

AGENCY: Department of Transportation.

ACTION: Notice of Order to Show Cause (Order 2016–7–6) DOT–OST–2016–0015.

SUMMARY: The Department of Transportation is directing all interested persons to show cause why it should not issue an order tentatively finding Rectrix Aviation, Inc., fit, willing, and able to provide scheduled passenger service as a commuter air carrier using small aircraft pursuant to Part 135 of the Federal Aviation Regulations.

DATES: Persons wishing to file objections should do so no later than July 25, 2016.

ADDRESSES: Objections and answers to objections should be filed in Docket DOT–OST–2016–0015 and addressed to U.S. Department of Transportation, Docket Operations (M–30, Room W12–140), 1200 New Jersey Avenue SE., West Building Ground Floor, Washington, DC 20590, and should be served upon the parties listed in Attachment A to the order.

FOR FURTHER INFORMATION CONTACT: Venk Paluvai, Office of Aviation Analysis (X–53, Room W86–497), U.S. Department of Transportation, 1200 New Jersey Avenue SE., Washington, DC 20590, (202) 366–5432.

Dated: July 8, 2016.

Jenny T. Rosenberg,

Acting Assistant Secretary for Aviation and International Affairs.

[FR Doc. 2016–16755 Filed 7–14–16; 8:45 am]

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FEDERAL REGISTER

Vol. 81 Friday,
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Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 410, 411, *et al.*

Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2017; Medicare Advantage Pricing Data Release; Medicare Advantage and Part D Medical Low Ratio Data Release; Medicare Advantage Provider Network Requirements; Expansion of Medicare Diabetes Prevention Program Model; Proposed Rules

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 410, 411, 414, 417, 422, 423, 424, 425, and 460

[CMS–1654–P]

RIN 0938–AS81

Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2017; Medicare Advantage Pricing Data Release; Medicare Advantage and Part D Medical Low Ratio Data Release; Medicare Advantage Provider Network Requirements; Expansion of Medicare Diabetes Prevention Program Model

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This major proposed rule addresses changes to the physician fee schedule and other Medicare Part B payment policies, such as changes to the Value Modifier, to ensure that our payment systems are updated to reflect changes in medical practice and the relative value of services, as well as changes in the statute. This proposed rule also includes proposals related to the Medicare Shared Saving Program, and the release of certain pricing data from Medicare Advantage bids and medical loss ratio reports from Medicare health and drug plans. In addition, this rule proposes to expand the Medicare Diabetes Prevention Program model.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on September 6, 2016.

ADDRESSES: In commenting, please refer to file code CMS–1654–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *www.regulations.gov.* Follow the instructions for "submitting a comment."

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1654–P, P.O. Box 8013, Baltimore, MD 21244–8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1654–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–7195 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

FOR FURTHER INFORMATION CONTACT:

Jessica Bruton, (410) 786–5991 for issues related to any physician payment issues not identified below.

Gail Addis, (410) 786–4522, for issues related to diabetes self-management training.

Jaime Hermansen, (410) 786–2064, for issues related to moderate sedation coding and anesthesia services.

Jessica Bruton, (410) 786–5991, for issues related to identification of potentially misvalued services.

Roberta Epps, (410) 786–4503, for issues related to PAMA section 218(a) policy and the transition from traditional x-ray imaging to digital radiography.

Ken Marsalek, (410) 786–4502, for issues related to telehealth services.

Ann Marshall, (410) 786–3059, for primary care issues related to chronic care management (CCM), burden reduction and evaluation and management services.

Emily Yoder, (410) 786–1804, for primary care issues related to resource intensive services and other primary care issues.

Lindsey Baldwin, (410) 786–1694, for primary care issues related to behavioral health integration services.

Geri Mondowney, (410) 786–4584, and Donta Henson, (410) 786–1947, for issues related to geographic practice cost indices.

Michael Soracoe, (410) 786–6312, for issues related to the target and phase-in provisions, the practice expense methodology, impacts, conversion factor, and the valuation of surgical procedures.

Pamela West, (410) 786–2302, for issues related to therapy.

Patrick Sartini, (410) 786–9252, for issues related to malpractice RVUs, radiation treatment, mammography and other imaging services.

Kathy Bryant, (410) 786–3448, for issues related to collecting data on resources used in furnishing global services.

Donta Henson, (410) 786–1947, for issues related to pathology and ophthalmology services.

Corinne Axelrod, (410) 786–5620, for issues related to rural health clinics or federally qualified health centers for comprehensive care management services furnished incident to.

Simone Dennis (410) 786–8409, for issues related to FQHC-specific market basket.

JoAnna Baldwin (410) 786–7205, or Sarah Fulton (410) 786–2749, for issues related to appropriate use criteria for advanced diagnostic imaging services.

Erin Skinner (410) 786–0157, for issues related to open payments.

Sean O'Grady (410) 786–2259, or Julie Uebersax (410) 786–9284, for issues related to release of pricing data from Medicare Advantage bids and release of medical loss ratio data submitted by Medicare Advantage organizations and Part D sponsors.

Sara Vitolo (410) 786–5714, for issues related to prohibition on billing qualified Medicare beneficiary individuals for Medicare cost-sharing.

Michelle Peterman (410) 786–2591, for issues on the technical correction for PQRS.

Katie Mucklow (410) 786–0537 or John Spiegel (410) 786–1909, for issues related to Provider Enrollment Medicare Advantage Program.

Jen Zhu (410) 786–3725, Carlye Burd (410) 786–1972, or Nina Brown (410)

786–6103, for issues related to Medicare Diabetes Prevention Program model expansion.

Rabia Khan or Terri Postma, (410) 786–8084 or *ACO@cms.hhs.gov,* for issues related to Medicare Shared Savings Program.

Sabrina Ahmed (410) 786–7499, or Fiona Larbi (410) 786–7224, for issues related to Value-based Payment Modifier and Physician Feedback Program.

Lisa Ohrin Wilson (410) 786–8852, or Gabriel Scott (410) 786–3928, for issues related to physician self-referral updates.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

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Regulations Text

Acronyms

In addition, because of the many organizations and terms to which we refer by acronym in this proposed rule, we are listing these acronyms and their corresponding terms in alphabetical order below:

A1c—Hemoglobin A1c
AAA—Abdominal aortic aneurysms
ACO—Accountable care organization
AMA—American Medical Association
ASC—Ambulatory surgical center
ATA—American Telehealth Association
ATRA—American Taxpayer Relief Act (Pub. L. 112–240)
AWV—Annual wellness visit
BBA—Balanced Budget Act of 1997 (Pub. L. 105–33)
BBRA—[Medicare, Medicaid and State Child Health Insurance Program] Balanced Budget Refinement Act of 1999 (Pub. L. 106–113)
CAD—Coronary artery disease
CAH—Critical access hospital
CBSA—Core-Based Statistical Area
CCM—Chronic care management
CEHRT—Certified EHR technology
CF—Conversion factor
CG—CAHPS—Clinician and Group Consumer Assessment of Healthcare Providers and Systems
CLFS—Clinical Laboratory Fee Schedule
CoA—Certificate of Accreditation
CoC—Certificate of Compliance
CoR—Certificate of Registration
CNM—Certified nurse-midwife
CP—Clinical psychologist
CPC—Comprehensive Primary Care
CPEP—Clinical Practice Expert Panel
CPT—[Physicians] Current Procedural Terminology (*CPT codes, descriptions and other data only are copyright 2015 American Medical Association. All rights reserved.*)
CQM—Clinical quality measure
CSW—Clinical social worker
CT—Computed tomography
CW—Certificate of Waiver
CY—Calendar year
DFAR—Defense Federal Acquisition Regulations
DHS— Designated health services
DM— Diabetes mellitus
DSMT—Diabetes self-management training
eCQM—Electronic clinical quality measures
ED—Emergency Department
EHR—Electronic health record
E/M—Evaluation and management
EMT—Emergency Medical Technician
EP—Eligible professional
eRx—Electronic prescribing
ESRD—End-stage renal disease
FAR—Federal Acquisition Regulations
FDA—Food and Drug Administration
FFS—Fee-for-service
FQHC—Federally qualified health center
FR—Federal Register
GAF—Geographic adjustment factor
GAO—Government Accountability Office
GPCI—Geographic practice cost index
GPO—Group purchasing organization
GPRO—Group practice reporting option
GTR—Genetic Testing Registry
HCPCS—Healthcare Common Procedure Coding System
HHS—[Department of] Health and Human Services
HOPD—Hospital outpatient department
HPSA—Health professional shortage area
IDTF—Independent diagnostic testing facility
IPPE—Initial preventive physical exam
IPPS—Inpatient Prospective Payment System
IQR—Inpatient Quality Reporting
ISO—Insurance service office
IT—Information technology
IWPUT—Intensity of work per unit of time
LCD—Local coverage determination
MA—Medicare Advantage
MAC—Medicare Administrative Contractor
MACRA—Medicare Access and CHIP Reauthorization Act of 2015 (Pub. L. 114–10)
MAP—Measure Applications Partnership
MAPCP—Multi-payer Advanced Primary Care Practice
MAV—Measure application validity [process]
MCP—Monthly capitation payment

MedPAC—Medicare Payment Advisory Commission
MEI—Medicare Economic Index
MFP—Multi-Factor Productivity
MIPPA—Medicare Improvements for Patients and Providers Act (Pub. L. 110–275)
MMA—Medicare Prescription Drug, Improvement and Modernization Act of 2003 (Pub. L. 108–173, enacted on December 8, 2003)
MP—Malpractice
MPPR—Multiple procedure payment reduction
MRA—Magnetic resonance angiography
MRI—Magnetic resonance imaging
MSA—Metropolitan Statistical Areas
MSPB—Medicare Spending per Beneficiary
MU—Meaningful use
NCD—National coverage determination
NCQDIS—National Coalition of Quality Diagnostic Imaging Services
NP—Nurse practitioner
NPI—National Provider Identifier
NPP—Nonphysician practitioner
NQS—National Quality Strategy
OACT—CMS's Office of the Actuary
OBRA '89—Omnibus Budget Reconciliation Act of 1989 (Pub. L. 101–239)
OBRA '90—Omnibus Budget Reconciliation Act of 1990 (Pub. L. 101–508)
OES—Occupational Employment Statistics
OMB—Office of Management and Budget
OPPS—Outpatient prospective payment system
OT—Occupational therapy
PA—Physician assistant
PAMA—Protecting Access to Medicare Act of 2014 (Pub. L. 113–93)
PC—Professional component
PCIP—Primary Care Incentive Payment
PE—Practice expense
PE/HR—Practice expense per hour
PEAC—Practice Expense Advisory Committee
PECOS—Provider Enrollment, Chain, and Ownership System
PFS—Physician Fee Schedule
PLI—Professional Liability Insurance
PMA—Premarket approval
PPM—Provider-Performed Microscopy
PQRS—Physician Quality Reporting System
PPIS—Physician Practice Expense Information Survey
PT—Physical therapy
PT—Proficiency Testing
PT/INR—Prothrombin Time/International Normalized Ratio
PY—Performance year
QA—Quality Assessment
QC—Quality Control
QCDR—Qualified clinical data registry
QRUR—Quality and Resources Use Report
RBRVS—Resource-based relative value scale
RFA—Regulatory Flexibility Act
RHC—Rural health clinic
RIA—Regulatory impact analysis
RUC—American Medical Association/Specialty Society Relative (Value) Update Committee
RUCA—Rural Urban Commuting Area
RVU—Relative value unit
SBA—Small Business Administration
SGR—Sustainable growth rate
SIM—State Innovation Model
SLP—Speech-language pathology
SMS—Socioeconomic Monitoring System
SNF—Skilled nursing facility
TAP—Technical Advisory Panel
TC—Technical component
TIN—Tax identification number
UAF—Update adjustment factor
UPIN—Unique Physician Identification Number
USPSTF—United States Preventive Services Task Force
VBP—Value-based purchasing
VM—Value-Based Payment Modifier

Addenda Available Only Through the Internet on the CMS Web Site

The PFS Addenda along with other supporting documents and tables referenced in this proposed rule are available through the Internet on the CMS Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.* Click on the link on the left side of the screen titled, "PFS Federal Regulations Notices" for a chronological list of PFS **Federal Register** and other related documents. For the CY 2017 PFS Proposed Rule, refer to item CMS–1654–P. Readers who experience any problems accessing any of the Addenda or other documents referenced in this rule and posted on the CMS Web site identified above should contact Jessica Bruton at (410) 786–5991.

CPT (Current Procedural Terminology) Copyright Notice

Throughout this proposed rule, we use CPT codes and descriptions to refer to a variety of services. We note that CPT codes and descriptions are copyright 2015 American Medical Association. All Rights Reserved. CPT is a registered trademark of the American Medical Association (AMA). Applicable Federal Acquisition Regulations (FAR) and Defense Federal Acquisition Regulations (DFAR) apply.

I. Executive Summary and Background

A. Executive Summary

1. Purpose

This major proposed rule proposes to revise payment polices under the Medicare Physician Fee Schedule (PFS) and make other policy changes related to Medicare Part B payment. These changes would be applicable to services furnished in CY 2017. In addition, this proposed rule includes proposals related to: the Medicare Shared Savings Program and release of pricing data submitted to CMS by Medicare Advantage (MA) organizations; and medical loss ratio reports submitted by MA plans and Part D plans. These additional proposals are addressed in section III. of this proposed rule.

2. Summary of the Major Provisions

The statute requires us to establish payments under the PFS based on national uniform relative value units (RVUs) that account for the relative resources used in furnishing a service. The statute requires that RVUs be established for three categories of resources: work, practice expense (PE); and malpractice (MP) expense; and, that we establish by regulation each year's payment amounts for all physicians' services paid under the PFS, incorporating geographic adjustments to reflect the variations in the costs of furnishing services in different geographic areas. In this major proposed rule, we are proposing to establish RVUs for CY 2017 for the PFS, and other Medicare Part B payment policies, to ensure that our payment systems are updated to reflect changes in medical practice and the relative value of services, as well as changes in the statute. In addition, this proposed rule includes discussions and proposals regarding:

- Potentially Misvalued PFS Codes.
- Telehealth Services.
- Establishing Values for New, Revised, and Misvalued Codes.
- Target for Relative Value Adjustments for Misvalued Services.
- Phase-in of Significant RVU Reductions.
- Chronic Care Management (CCM) and Transitional Care Management (TCM) Supervision Requirements in Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs).
- FQHC-Specific Market Basket.
- Appropriate Use Criteria for Advanced Diagnostic Imaging Services.
- Reports of Payments or Other Transfers of Value to Covered Recipients: Solicitation of Public Comments.
- Release of Part C Medicare Advantage Bid Pricing Data and Part C and Part D Medical Loss Ratio (MLR) Data.
- Prohibition on Billing Qualified Medicare Beneficiary Individuals for Medicare Cost-Sharing.
- Recoupment or Offset of Payments to Providers Sharing the Same Taxpayer Identification Number.
- Accountable Care Organization (ACO) Participants Who Report Physician Quality Reporting System (PQRS) Quality Measures Separately.
- Medicare Advantage Provider Enrollment.
- Proposed Expansion of the Diabetes Prevention Program (DPP) Model.
- Medicare Shared Savings Program.
- Value-Based Payment Modifier and the Physician Feedback Program.
- Physician Self-referral Updates.

3. Summary of Costs and Benefits

The statute requires that annual adjustments to PFS RVUs may not cause annual estimated expenditures to differ by more than $20 million from what they would have been had the adjustments not been made. If adjustments to RVUs would cause expenditures to change by more than $20 million, we must make adjustments to preserve budget neutrality. These adjustments can affect the distribution of Medicare expenditures across specialties. In addition, several changes proposed in this proposed rule would affect the specialty distribution of Medicare expenditures. When considering the combined impact of proposed work, PE, and MP RVU changes, the projected payment impacts would be small for most specialties; however, the impact would be larger for a few specialties.

We have determined that this major proposed rule is economically significant. For a detailed discussion of the economic impacts, see section VI. of this proposed rule.

B. Background

Since January 1, 1992, Medicare has paid for physicians' services under section 1848 of the Social Security Act (the Act), "Payment for Physicians' Services." The system relies on national relative values that are established for work, PE, and MP, which are adjusted for geographic cost variations. These values are multiplied by a conversion factor (CF) to convert the RVUs into payment rates. The concepts and methodology underlying the PFS were enacted as part of the Omnibus Budget Reconciliation Act of 1989 (Pub. L. 101–239, enacted on December 19, 1989) (OBRA '89), and the Omnibus Budget Reconciliation Act of 1990 (Pub. L. 101–508, enacted on November 5, 1990) (OBRA '90). The final rule published on November 25, 1991 (56 FR 59502) set forth the first fee schedule used for payment for physicians' services.

We note that throughout this major proposed rule, unless otherwise noted, the term "practitioner" is used to describe both physicians and nonphysician practitioners (NPPs) who are permitted to bill Medicare under the PFS for services furnished to Medicare beneficiaries.

1. Development of the Relative Values

a. Work RVUs

The work RVUs established for the initial fee schedule, which was implemented on January 1, 1992, were developed with extensive input from the physician community. A research team at the Harvard School of Public Health developed the original work RVUs for most codes under a cooperative agreement with the Department of Health and Human Services (HHS). In constructing the code-specific vignettes used in determining the original physician work RVUs, Harvard worked with panels of experts, both inside and outside the federal government, and obtained input from numerous physician specialty groups.

As specified in section 1848(c)(1)(A) of the Act, the work component of physicians' services means the portion of the resources used in furnishing the service that reflects physician time and intensity. We establish work RVUs for new, revised and potentially misvalued codes based on our review of information that generally includes, but is not limited to, recommendations received from the American Medical Association/Specialty Society Relative Value Update Committee (RUC), the Health Care Professionals Advisory Committee (HCPAC), the Medicare Payment Advisory Commission (MedPAC), and other public commenters; medical literature and comparative databases; as well as a comparison of the work for other codes within the Medicare PFS, and consultation with other physicians and health care professionals within CMS and the federal government. We also assess the methodology and data used to develop the recommendations submitted to us by the RUC and other public commenters, and the rationale for their recommendations. In the CY 2011 PFS final rule with comment period (75 FR 73328 through 73329), we discussed a variety of methodologies and approaches used to develop work RVUs, including survey data, building blocks, crosswalk to key reference or similar codes, and magnitude estimation. More information on these issues is available in that rule.

b. Practice Expense RVUs

Initially, only the work RVUs were resource-based, and the PE and MP RVUs were based on average allowable charges. Section 121 of the Social Security Act Amendments of 1994 (Pub. L. 103–432, enacted on October 31, 1994), amended section 1848(c)(2)(C)(ii) of the Act and required us to develop resource-based PE RVUs for each physicians' service beginning in 1998. We were required to consider general categories of expenses (such as office rent and wages of personnel, but excluding malpractice expenses) comprising PEs. The PE RVUs continue to represent the portion of these resources involved in furnishing PFS services.

Originally, the resource-based method was to be used beginning in 1998, but section 4505(a) of the Balanced Budget Act of 1997 (Pub. L. 105–33, enacted on August 5, 1997) (BBA) delayed implementation of the resource-based PE RVU system until January 1, 1999. In addition, section 4505(b) of the BBA provided for a 4-year transition period from the charge-based PE RVUs to the resource-based PE RVUs.

We established the resource-based PE RVUs for each physicians' service in a final rule, published on November 2, 1998 (63 FR 58814), effective for services furnished in CY 1999. Based on the requirement to transition to a resource-based system for PE over a 4-year period, payment rates were not fully based upon resource-based PE RVUs until CY 2002. This resource-based system was based on two significant sources of actual PE data: the Clinical Practice Expert Panel (CPEP) data; and the AMA's Socioeconomic Monitoring System (SMS) data. (These data sources are described in greater detail in the CY 2012 final rule with comment period (76 FR 73033).

Separate PE RVUs are established for services furnished in facility settings, such as a hospital outpatient department (HOPD) or an ambulatory surgical center (ASC), and in nonfacility settings, such as a physician's office. The nonfacility RVUs reflect all of the direct and indirect PEs involved in furnishing a service described by a particular HCPCS code. The difference, if any, in these PE RVUs generally results in a higher payment in the nonfacility setting because in the facility settings some costs are borne by the facility. Medicare's payment to the facility (such as the outpatient prospective payment system (OPPS) payment to the HOPD) would reflect costs typically incurred by the facility. Thus, payment associated with those facility resources is not made under the PFS.

Section 212 of the Balanced Budget Refinement Act of 1999 (Pub. L. 106–113, enacted on November 29, 1999) (BBRA) directed the Secretary of Health and Human Services (the Secretary) to establish a process under which we accept and use, to the maximum extent practicable and consistent with sound data practices, data collected or developed by entities and organizations to supplement the data we normally collect in determining the PE component. On May 3, 2000, we published the interim final rule (65 FR 25664) that set forth the criteria for the submission of these supplemental PE survey data. The criteria were modified in response to comments received, and published in the **Federal Register** (65 FR 65376) as part of a November 1, 2000 final rule. The PFS final rules published in 2001 and 2003, respectively, (66 FR 55246 and 68 FR 63196) extended the period during which we would accept these supplemental data through March 1, 2005.

In the CY 2007 PFS final rule with comment period (71 FR 69624), we revised the methodology for calculating direct PE RVUs from the top-down to the bottom-up methodology beginning in CY 2007. We adopted a 4-year transition to the new PE RVUs. This transition was completed for CY 2010. In the CY 2010 PFS final rule with comment period, we updated the practice expense per hour (PE/HR) data that are used in the calculation of PE RVUs for most specialties (74 FR 61749). In CY 2010, we began a 4-year transition to the new PE RVUs using the updated PE/HR data, which was completed for CY 2013.

c. Malpractice RVUs

Section 4505(f) of the BBA amended section 1848(c) of the Act to require that we implement resource-based MP RVUs for services furnished on or after CY 2000. The resource-based MP RVUs were implemented in the PFS final rule with comment period published November 2, 1999 (64 FR 59380). The MP RVUs are based on commercial and physician-owned insurers' malpractice insurance premium data from all the states, the District of Columbia, and Puerto Rico. For more information on MP RVUs, see section II.B.2. of this proposed rule.

d. Refinements to the RVUs

Section 1848(c)(2)(B)(i) of the Act requires that we review RVUs no less often than every 5 years. Prior to CY 2013, we conducted periodic reviews of work RVUs and PE RVUs independently. We completed five-year reviews of work RVUs that were effective for calendar years 1997, 2002, 2007, and 2012.

Although refinements to the direct PE inputs initially relied heavily on input from the RUC Practice Expense Advisory Committee (PEAC), the shifts to the bottom-up PE methodology in CY 2007 and to the use of the updated PE/HR data in CY 2010 have resulted in significant refinements to the PE RVUs in recent years.

In the CY 2012 PFS final rule with comment period (76 FR 73057), we finalized a proposal to consolidate reviews of work and PE RVUs under section 1848(c)(2)(B) of the Act and reviews of potentially misvalued codes under section 1848(c)(2)(K) of the Act into one annual process.

In addition to the five-year reviews, beginning for CY 2009, CMS and the RUC have identified and reviewed a number of potentially misvalued codes on an annual basis based on various identification screens. This annual review of work and PE RVUs for potentially misvalued codes was supplemented by the amendments to section 1848 of the Act, as enacted by section 3134 of the Affordable Care Act, which requires the agency to periodically identify, review and adjust values for potentially misvalued codes.

e. Application of Budget Neutrality to Adjustments of RVUs

As described in section VI.C. of this proposed rule, in accordance with section 1848(c)(2)(B)(ii)(II) of the Act, if revisions to the RVUs cause expenditures for the year to change by more than $20 million, we make adjustments to ensure that expenditures did not increase or decrease by more than $20 million.

2. Calculation of Payments Based on RVUs

To calculate the payment for each service, the components of the fee schedule (work, PE, and MP RVUs) are adjusted by geographic practice cost indices (GPCIs) to reflect the variations in the costs of furnishing the services. The GPCIs reflect the relative costs of work, PE, and MP in an area compared to the national average costs for each component.

RVUs are converted to dollar amounts through the application of a CF, which is calculated based on a statutory formula by CMS's Office of the Actuary (OACT). The formula for calculating the Medicare fee schedule payment amount for a given service and fee schedule area can be expressed as:

Payment = [(RVU work × GPCI work) + (RVU PE × GPCI PE) + (RVU MP × GPCI MP)] × CF.

3. Separate Fee Schedule Methodology for Anesthesia Services

Section 1848(b)(2)(B) of the Act specifies that the fee schedule amounts for anesthesia services are to be based on a uniform relative value guide, with appropriate adjustment of an anesthesia conversion factor, in a manner to ensure that fee schedule amounts for anesthesia services are consistent with those for other services of comparable value. Therefore, there is a separate fee schedule methodology for anesthesia services. Specifically, we establish a separate conversion factor for anesthesia services and we utilize the uniform relative value guide, or base units, as well as time units, to calculate the fee schedule amounts for anesthesia services. Since anesthesia services are not valued using RVUs, a separate methodology for locality adjustments is also necessary. This involves an adjustment to the national anesthesia CF for each payment locality.

4. Most Recent Changes to the Fee Schedule

Section 220(d) of the Protecting Access to Medicare Act of 2014 (Pub. L. 113–93, enacted on April 1, 2014) (PAMA) added a new subparagraph (O) to section 1848(c)(2) of the Act to establish an annual target for reductions in PFS expenditures resulting from adjustments to relative values of misvalued codes. If the estimated net reduction in expenditures for a year is equal to or greater than the target for that year, the provision specifies that reduced expenditures attributable to such adjustments shall be redistributed in a budget-neutral manner within the PFS. The provision specifies that the amount by which such reduced expenditures exceed the target for a given year shall be treated as a reduction in expenditures for the subsequent year for purposes of determining whether the target for the subsequent year has been met. The provision also specifies that an amount equal to the difference between the target and the estimated net reduction in expenditures, called the target recapture amount, shall not be taken into account when applying the budget neutrality requirements specified in section 1848(c)(2)(B)(ii)(II) of the Act. The PAMA amendments originally made the target provisions applicable for CYs 2017 through 2020 and set the target for reduced expenditures at 0.5 percent of estimated expenditures under the PFS for each of those 4 years.

Subsequently, section 202 of the Achieving a Better Life Experience Act of 2014 (Division B of Pub. L. 113–295, enacted December 19, 2014) (ABLE) accelerated the application of the target, amending section 1848(c)(2)(O) of the Act to specify that target provisions apply for CYs 2016, 2017, and 2018; and setting a 1 percent target for reduced expenditures for CY 2016 and a 0.5 percent target for CYs 2017 and 2018. The implementation of the target legislation was finalized in the CY 2016 PFS final rule with comment period, and proposed revisions are discussed in section II.G. of this proposed rule.

Section 1848(c)(7) of the Act, as added by section 220(e) of the PAMA, specified that for services that are not new or revised codes, if the total RVUs for a service for a year would otherwise be decreased by an estimated 20 percent or more as compared to the total RVUs for the previous year, the applicable adjustments in work, PE, and MP RVUs shall be phased in over a 2-year period. Section 220(e) of the PAMA required the phase-in of RVU reductions of 20 percent or more to begin for 2017. Section 1848(c)(7) of the Act was later amended by section 202 of the ABLE Act to require instead that the phase-in must begin in CY 2016. The implementation of the phase-in legislation was finalized in the CY 2016 PFS final rule with comment period and proposed revisions in this year's rulemaking are discussed in section II.H. of this proposed rule.

II. Provisions of the Proposed Rule for PFS

A. Determination of Practice Expense (PE) Relative Value Units (RVUs)

1. Overview

Practice expense (PE) is the portion of the resources used in furnishing a service that reflects the general categories of physician and practitioner expenses, such as office rent and personnel wages, but excluding malpractice expenses, as specified in section 1848(c)(1)(B) of the Act. As required by section 1848(c)(2)(C)(ii) of the Act, we use a resource-based system for determining PE RVUs for each physicians' service. We develop PE RVUs by considering the direct and indirect practice resources involved in furnishing each service. Direct expense categories include clinical labor, medical supplies, and medical equipment. Indirect expenses include administrative labor, office expense, and all other expenses. The sections that follow provide more detailed information about the methodology for translating the resources involved in furnishing each service into service-specific PE RVUs. We refer readers to the CY 2010 PFS final rule with comment period (74 FR 61743 through 61748) for a more detailed explanation of the PE methodology.

2. Practice Expense Methodology

a. Direct Practice Expense

We determine the direct PE for a specific service by adding the costs of the direct resources (that is, the clinical staff, medical supplies, and medical equipment) typically involved with furnishing that service. The costs of the resources are calculated using the refined direct PE inputs assigned to each CPT code in our PE database, which are generally based on our review of recommendations received from the RUC and those provided in response to public comment periods. For a detailed explanation of the direct PE methodology, including examples, we refer readers to the Five-Year Review of Work Relative Value Units under the PFS and Proposed Changes to the Practice Expense Methodology proposed notice (71 FR 37242) and the CY 2007 PFS final rule with comment period (71 FR 69629).

b. Indirect Practice Expense per Hour Data

We use survey data on indirect PEs incurred per hour worked in developing the indirect portion of the PE RVUs. Prior to CY 2010, we primarily used the practice expense per hour (PE/HR) by specialty that was obtained from the AMA's Socioeconomic Monitoring Surveys (SMS). The AMA administered a new survey in CY 2007 and CY 2008, the Physician Practice Expense Information Survey (PPIS). The PPIS is a multispecialty, nationally representative, PE survey of both physicians and nonphysician practitioners (NPPs) paid under the PFS using a survey instrument and methods highly consistent with those used for the SMS and the supplemental surveys. The PPIS gathered information from 3,656 respondents across 51 physician specialty and health care professional groups. We believe the PPIS is the most comprehensive source of PE survey information available. We used the PPIS data to update the PE/HR data for the CY 2010 PFS for almost all of the Medicare-recognized specialties that participated in the survey.

When we began using the PPIS data in CY 2010, we did not change the PE RVU methodology itself or the manner in which the PE/HR data are used in that methodology. We only updated the PE/HR data based on the new survey. Furthermore, as we explained in the CY 2010 PFS final rule with comment period (74 FR 61751), because of the magnitude of payment reductions for some specialties resulting from the use of the PPIS data, we transitioned its use over a 4-year period from the previous PE RVUs to the PE RVUs developed using the new PPIS data. As provided in the CY 2010 PFS final rule with comment period (74 FR 61751), the transition to the PPIS data was complete for CY 2013. Therefore, PE RVUs from CY 2013 forward are developed based entirely on the PPIS data, except as noted in this section.

Section 1848(c)(2)(H)(i) of the Act requires us to use the medical oncology supplemental survey data submitted in 2003 for oncology drug administration services. Therefore, the PE/HR for medical oncology, hematology, and hematology/oncology reflects the continued use of these supplemental survey data.

Supplemental survey data on independent labs from the College of American Pathologists were implemented for payments beginning in CY 2005. Supplemental survey data from the National Coalition of Quality Diagnostic Imaging Services (NCQDIS), representing independent diagnostic testing facilities (IDTFs), were blended with supplementary survey data from the American College of Radiology (ACR) and implemented for payments beginning in CY 2007. Neither IDTFs, nor independent labs, participated in the PPIS. Therefore, we continue to use the PE/HR that was developed from their supplemental survey data. Consistent with our past practice, the previous indirect PE/HR values from the supplemental surveys for these specialties were updated to CY 2006 using the Medicare Economic Index (MEI) to put them on a comparable basis with the PPIS data.

We also do not use the PPIS data for reproductive endocrinology and spine surgery since these specialties currently are not separately recognized by Medicare, nor do we have a method to blend the PPIS data with Medicare-recognized specialty data.

Previously, we established PE/HR values for various specialties without SMS or supplemental survey data by crosswalking them to other similar specialties to estimate a proxy PE/HR. For specialties that were part of the PPIS for which we previously used a crosswalked PE/HR, we instead used the PPIS-based PE/HR. We continue previous crosswalks for specialties that did not participate in the PPIS. However, beginning in CY 2010 we changed the PE/HR crosswalk for portable X-ray suppliers from radiology to IDTF, a more appropriate crosswalk because these specialties are more similar to each other for work time.

For registered dietician services, the resource-based PE RVUs have been calculated in accordance with the final policy that crosswalks the specialty to the "All Physicians" PE/HR data, as adopted in the CY 2010 PFS final rule with comment period (74 FR 61752) and discussed in more detail in the CY 2011 PFS final rule with comment period (75 FR 73183). We have incorporated the available utilization data for interventional cardiology, which became a recognized Medicare specialty during 2014. We finalized the use of a proxy PE/HR value for interventional cardiology in the CY 2016 final rule with comment period (80 FR 70892), as there are no PPIS data for this specialty, by crosswalking the PE/HR for from

Cardiology, since the specialties furnish similar services in the Medicare claims data.

c. Allocation of PE to Services

To establish PE RVUs for specific services, it is necessary to establish the direct and indirect PE associated with each service.

(1) Direct Costs

The relative relationship between the direct cost portions of the PE RVUs for any two services is determined by the relative relationship between the sum of the direct cost resources (that is, the clinical staff, medical supplies, and medical equipment) typically involved with furnishing each of the services. The costs of these resources are calculated from the refined direct PE inputs in our PE database. For example, if one service has a direct cost sum of $400 from our PE database and another service has a direct cost sum of $200, the direct portion of the PE RVUs of the first service would be twice as much as the direct portion of the PE RVUs for the second service.

(2) Indirect Costs

Section II.A.2.b. of this proposed rule describes the current data sources for specialty-specific indirect costs used in our PE calculations. We allocated the indirect costs to the code level on the basis of the direct costs specifically associated with a code and the greater of either the clinical labor costs or the work RVUs. We also incorporated the survey data described earlier in the PE/HR discussion. The general approach to developing the indirect portion of the PE RVUs is as follows:

- For a given service, we used the direct portion of the PE RVUs calculated as previously described and the average percentage that direct costs represent of total costs (based on survey data) across the specialties that furnish the service to determine an initial indirect allocator. That is, the initial indirect allocator is calculated so that the direct costs equal the average percentage of direct costs of those specialties furnishing the service. For example, if the direct portion of the PE RVUs for a given service is 2.00 and direct costs, on average, represented 25 percent of total costs for the specialties that furnished the service, the initial indirect allocator would be calculated so that it equals 75 percent of the total PE RVUs. Thus, in this example, the initial indirect allocator would equal 6.00, resulting in a total PE RVUs of 8.00 (2.00 is 25 percent of 8.00 and 6.00 is 75 percent of 8.00).
- Next, we added the greater of the work RVUs or clinical labor portion of the direct portion of the PE RVUs to this initial indirect allocator. In our example, if this service had work RVUs of 4.00 and the clinical labor portion of the direct PE RVUs was 1.50, we would add 4.00 (since the 4.00 work RVUs are greater than the 1.50 clinical labor portion) to the initial indirect allocator of 6.00 to get an indirect allocator of 10.00. In the absence of any further use of the survey data, the relative relationship between the indirect cost portions of the PE RVUs for any two services would be determined by the relative relationship between these indirect cost allocators. For example, if one service had an indirect cost allocator of 10.00 and another service had an indirect cost allocator of 5.00, the indirect portion of the PE RVUs of the first service would be twice as great as the indirect portion of the PE RVUs for the second service.
- Next, we incorporated the specialty-specific indirect PE/HR data into the calculation. In our example, if, based on the survey data, the average indirect cost of the specialties furnishing the first service with an allocator of 10.00 was half of the average indirect cost of the specialties furnishing the second service with an indirect allocator of 5.00, the indirect portion of the PE RVUs of the first service would be equal to that of the second service.

(3) Facility and Nonfacility Costs

For procedures that can be furnished in a physician's office, as well as in a hospital or other facility setting, we establish two PE RVUs: Facility, and nonfacility. The methodology for calculating PE RVUs is the same for both the facility and nonfacility RVUs, but is applied independently to yield two separate PE RVUs. In calculating the PE RVUs for services furnished in a facility, we do not include resources that would generally not be provided by physicians when furnishing the service. For this reason, the facility PE RVUs are generally lower than the nonfacility PE RVUs. Medicare makes a separate payment to the facility for its costs of furnishing a service.

(4) Services With Technical Components (TCs) and Professional Components (PCs)

Diagnostic services are generally composed of two components: A professional component (PC) and a technical component (TC). The PC and TC may be furnished independently or by different providers, or they may be furnished together as a ''global'' service. When services have separately billable PC and TC components, the payment for the global service equals the sum of the payment for the TC and PC. To achieve this we use a weighted average of the ratio of indirect to direct costs across all the specialties that furnish the global service, TCs, and PCs; that is, we apply the same weighted average indirect percentage factor to allocate indirect expenses to the global service, PCs, and TCs for a service. (The direct PE RVUs for the TC and PC sum to the global.)

(5) PE RVU Methodology

For a more detailed description of the PE RVU methodology, we refer readers to the CY 2010 PFS final rule with comment period (74 FR 61745 through 61746). We also direct interested readers to the file called ''Calculation of PE RVUs under Methodology for Selected Codes'' which is available on our Web site under downloads for the CY 2017 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.* This file contains a table that illustrates the calculation of PE RVUs as described below for individual PFS codes.

(a) Setup File

First, we create a setup file for the PE methodology. The setup file contains the direct cost inputs, the utilization for each procedure code at the specialty and facility/nonfacility place of service level, and the specialty-specific PE/HR data calculated from the surveys.

(b) Calculate the Direct Cost PE RVUs

Sum the costs of each direct input.

Step 1: Sum the direct costs of the inputs for each service.

Step 2: Calculate the aggregate pool of direct PE costs for the current year. We set the aggregate pool of PE costs equal to the product of the ratio of the current aggregate PE RVUs to current aggregate work RVUs and the proposed aggregate work RVUs.

Step 3: Calculate the aggregate pool of direct PE costs for use in ratesetting. This is the product of the aggregate direct costs for all services from Step 1 and the utilization data for that service.

Step 4: Using the results of Step 2 and Step 3, calculate a direct PE scaling factor to ensure that the aggregate pool of direct PE costs calculated in Step 3 does not vary from the aggregate pool of direct PE costs for the current year. Apply the scaling factor to the direct costs for each service (as calculated in Step 1).

Step 5: Convert the results of Step 4 to an RVU scale for each service. To do this, divide the results of Step 4 by the CF. Note that the actual value of the CF used in this calculation does not influence the final direct cost PE RVUs, as long as the same CF is used in Step 2 and Step 5. Different CFs will result in different direct PE scaling factors, but this has no effect on the final direct cost PE RVUs since changes in the CFs and changes in the associated direct scaling factors offset one another.

(c) Create the Indirect Cost PE RVUs

Create indirect allocators.

Step 6: Based on the survey data, calculate direct and indirect PE percentages for each physician specialty.

Step 7: Calculate direct and indirect PE percentages at the service level by taking a weighted average of the results of Step 6 for the specialties that furnish the service. Note that for services with TCs and PCs, the direct and indirect percentages for a given service do not vary by the PC, TC, and global service.

We use an average of the 3 most recent years of available Medicare claims data to determine the specialty mix assigned to each code. As we stated in the CY 2016 final rule with comment period (80 FR 70894), we believe that the 3-year average will mitigate the need to use dominant or expected specialty instead of the claims data. Because we are incorporating CY 2015 claims data for use in the CY 2017 proposed rates, we believe that the proposed PE RVUs associated with the CY 2017 PFS proposed rule provide a first opportunity to determine whether service-level overrides of claims data are necessary. Currently, in the development of PE RVUs we apply only the overrides that also apply to the MP RVU calculation. Since the proposed PE RVUs include a new year of claims into the 3 year average for the first time, we are seeking comment on the proposed CY 2017 PFS rates and whether or not the incorporation of a new year of utilization data into a three year average mitigates the need for alternative service-level overrides such as a claims-based approach (dominant specialty) or stakeholder-recommended approach (expected specialty) in the development of PE (and MP) RVUs for low-volume codes. Prior year RVUs are available at several locations on the PFS Web site located at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/*.

Step 8: Calculate the service level allocators for the indirect PEs based on the percentages calculated in Step 7. The indirect PEs are allocated based on the three components: The direct PE RVUs; the clinical labor PE RVUs; and the work RVUs.

For most services the indirect allocator is: Indirect PE percentage * (direct PE RVUs/direct percentage) + work RVUs.

There are two situations where this formula is modified:

- If the service is a global service (that is, a service with global, professional, and technical components), then the indirect PE allocator is: Indirect percentage (direct PE RVUs/direct percentage) + clinical labor PE RVUs + work RVUs.
- If the clinical labor PE RVUs exceed the work RVUs (and the service is not a global service), then the indirect allocator is: Indirect PE percentage (direct PE RVUs/direct percentage) + clinical labor PE RVUs. (*Note:* For global services, the indirect PE allocator is based on both the work RVUs and the clinical labor PE RVUs. We do this to recognize that, for the PC service, indirect PEs will be allocated using the work RVUs, and for the TC service, indirect PEs will be allocated using the direct PE RVUs and the clinical labor PE RVUs. This also allows the global component RVUs to equal the sum of the PC and TC RVUs.)

For presentation purposes, in the examples in the download file called "Calculation of PE RVUs under Methodology for Selected Codes", the formulas were divided into two parts for each service.

- The first part does not vary by service and is the indirect percentage (direct PE RVUs/direct percentage).
- The second part is either the work RVU, clinical labor PE RVU, or both depending on whether the service is a global service and whether the clinical PE RVUs exceed the work RVUs (as described earlier in this step).

Apply a scaling adjustment to the indirect allocators.

Step 9: Calculate the current aggregate pool of indirect PE RVUs by multiplying the result of step 8 by the average indirect PE percentage from the survey data.

Step 10: Calculate an aggregate pool of indirect PE RVUs for all PFS services by adding the product of the indirect PE allocators for a service from Step 8 and the utilization data for that service.

Step 11: Using the results of Step 9 and Step 10, calculate an indirect PE adjustment so that the aggregate indirect allocation does not exceed the available aggregate indirect PE RVUs and apply it to indirect allocators calculated in Step 8. Calculate the indirect practice cost index.

Step 12: Using the results of Step 11, calculate aggregate pools of specialty-specific adjusted indirect PE allocators for all PFS services for a specialty by adding the product of the adjusted indirect PE allocator for each service and the utilization data for that service.

Step 13: Using the specialty-specific indirect PE/HR data, calculate specialty-specific aggregate pools of indirect PE for all PFS services for that specialty by adding the product of the indirect PE/HR for the specialty, the work time for the service, and the specialty's utilization for the service across all services furnished by the specialty.

Step 14: Using the results of Step 12 and Step 13, calculate the specialty-specific indirect PE scaling factors.

Step 15: Using the results of Step 14, calculate an indirect practice cost index at the specialty level by dividing each specialty-specific indirect scaling factor by the average indirect scaling factor for the entire PFS.

Step 16: Calculate the indirect practice cost index at the service level to ensure the capture of all indirect costs. Calculate a weighted average of the practice cost index values for the specialties that furnish the service. (*Note:* For services with TCs and PCs, we calculate the indirect practice cost index across the global service, PCs, and TCs. Under this method, the indirect practice cost index for a given service (for example, echocardiogram) does not vary by the PC, TC, and global service.)

Step 17: Apply the service level indirect practice cost index calculated in Step 16 to the service level adjusted indirect allocators calculated in Step 11 to get the indirect PE RVUs.

(d) Calculate the Final PE RVUs

Step 18: Add the direct PE RVUs from Step 5 to the indirect PE RVUs from Step 17 and apply the final PE budget neutrality (BN) adjustment. The final PE BN adjustment is calculated by comparing the sum of steps 5 and 17 of to the proposed aggregate work RVUs scaled by the ratio of current aggregate PE and work RVUs. This adjustment ensures that all PE RVUs in the PFS account for the fact that certain specialties are excluded from the calculation of PE RVUs but included in maintaining overall PFS budget neutrality. (See "Specialties excluded from ratesetting calculation" later in this section.)

(e) Setup File Information

- *Specialties excluded from ratesetting calculation:* For the purposes of calculating the PE RVUs, we exclude certain specialties, such as certain nonphysician practitioners paid at a percentage of the PFS and low-volume specialties, from the calculation. These specialties are included for the purposes of calculating the BN adjustment. They are displayed in Table 1.

TABLE 1—SPECIALTIES EXCLUDED FROM RATESETTING CALCULATION

Specialty code	Specialty description
49	Ambulatory surgical center.
50	Nurse practitioner.
51	Medical supply company with certified orthotist.
52	Medical supply company with certified prosthetist.
53	Medical supply company with certified prosthetist-orthotist.
54	Medical supply company not included in 51, 52, or 53.
55	Individual certified orthotist.
56	Individual certified prosthetist.
57	Individual certified prosthetist-orthotist.
58	Medical supply company with registered pharmacist.
59	Ambulance service supplier, *e.g.*, private ambulance companies, funeral homes, etc.
60	Public health or welfare agencies.
61	Voluntary health or charitable agencies.
73	Mass immunization roster biller.
74	Radiation therapy centers.
87	All other suppliers (*e.g.*, drug and department stores).
88	Unknown supplier/provider specialty.
89	Certified clinical nurse specialist.
96	Optician.
97	Physician assistant.
A0	Hospital.
A1	SNF.
A2	Intermediate care nursing facility.
A3	Nursing facility, other.
A4	HHA.
A5	Pharmacy.
A6	Medical supply company with respiratory therapist.
A7	Department store.
B2	Pedorthic personnel.
B3	Medical supply company with pedorthic personnel.

- *Crosswalk certain low volume physician specialties:* Crosswalk the utilization of certain specialties with relatively low PFS utilization to the associated specialties.
- *Physical therapy utilization:* Crosswalk the utilization associated with all physical therapy services to the specialty of physical therapy.
- *Identify professional and technical services not identified under the usual TC and 26 modifiers:* Flag the services that are PC and TC services but do not use TC and 26 modifiers (for example, electrocardiograms). This flag associates the PC and TC with the associated global code for use in creating the indirect PE RVUs. For example, the professional service, CPT code 93010 (Electrocardiogram, routine ECG with at least 12 leads; interpretation and report only), is associated with the global service, CPT code 93000 (Electrocardiogram, routine ECG with at least 12 leads; with interpretation and report).
- *Payment modifiers:* Payment modifiers are accounted for in the creation of the file consistent with current payment policy as implemented in claims processing. For example, services billed with the assistant at surgery modifier are paid 16 percent of the PFS amount for that service; therefore, the utilization file is modified to only account for 16 percent of any service that contains the assistant at surgery modifier. Similarly, for those services to which volume adjustments are made to account for the payment modifiers, time adjustments are applied as well. For time adjustments to surgical services, the intraoperative portion in the work time file is used; where it is not present, the intraoperative percentage from the payment files used by contractors to process Medicare claims is used instead. Where neither is available, we use the payment adjustment ratio to adjust the time accordingly. Table 2 details the manner in which the modifiers are applied.

TABLE 2—APPLICATION OF PAYMENT MODIFIERS TO UTILIZATION FILES

Modifier	Description	Volume adjustment	Time adjustment
80, 81, 82	Assistant at Surgery	16%	Intraoperative portion.
AS	Assistant at Surgery—Physician Assistant.	14% (85% * 16%)	Intraoperative portion.
50 or LT and RT	Bilateral Surgery	150%	150% of work time.
51	Multiple Procedure	50%	Intraoperative portion.
52	Reduced Services	50%	50%.
53	Discontinued Procedure	50%	50%.
54	Intraoperative Care only	Preoperative + Intraoperative Percentages on the payment files used by Medicare contractors to process Medicare claims.	Preoperative + Intraoperative portion.
55	Postoperative Care only	Postoperative Percentage on the payment files used by Medicare contractors to process Medicare claims.	Postoperative portion.

TABLE 2—APPLICATION OF PAYMENT MODIFIERS TO UTILIZATION FILES—Continued

Modifier	Description	Volume adjustment	Time adjustment
62	Co-surgeons	62.5%	50%.
66	Team Surgeons	33%	33%.

We also make adjustments to volume and time that correspond to other payment rules, including special multiple procedure endoscopy rules and multiple procedure payment reductions (MPPRs). We note that section 1848(c)(2)(B)(v) of the Act exempts certain reduced payments for multiple imaging procedures and multiple therapy services from the BN calculation under section 1848(c)(2)(B)(ii)(II) of the Act. These MPPRs are not included in the development of the RVUs.

For anesthesia services, we do not apply adjustments to volume since we use the average allowed charge when simulating RVUs; therefore, the RVUs as calculated already reflect the payments as adjusted by modifiers, and no volume adjustments are necessary. However, a time adjustment of 33 percent is made only for medical direction of two to four cases since that is the only situation where a single practitioner is involved with multiple beneficiaries concurrently, so that counting each service without regard to the overlap with other services would overstate the amount of time spent by the practitioner furnishing these services.

- *Work RVUs:* The setup file contains the work RVUs from this proposed rule.

(6) Equipment Cost Per Minute

The equipment cost per minute is calculated as:

$$(1/(\text{minutes per year} * \text{usage})) * \text{price} * ((\text{interest rate}/(1 - (1/((1 + \text{interest rate})^{\wedge}\ \text{life of equipment})))) + \text{maintenance})$$

Where:

minutes per year = maximum minutes per year if usage were continuous (that is, usage = 1); generally 150,000 minutes.
usage = variable, see discussion below.
price = price of the particular piece of equipment.
life of equipment = useful life of the particular piece of equipment.
maintenance = factor for maintenance; 0.05.
interest rate = variable, see discussion below.

Usage: We currently use an equipment utilization rate assumption of 50 percent for most equipment, with the exception of expensive diagnostic imaging equipment, for which we use a 90 percent assumption as required by section 1848(b)(4)(C) of the Act.

Stakeholders have often suggested that particular equipment items are used less frequently than 50 percent of the time in the typical setting and that CMS should reduce the equipment utilization rate based on these recommendations. We appreciate and share stakeholders' interest in using the most accurate assumption regarding the equipment utilization rate for particular equipment items. However, we believe that absent robust, objective, auditable data regarding the use of particular items, the 50 percent assumption is the most appropriate within the relative value system. We welcome the submission of data that illustrates an alternative rate.

Maintenance: This factor for maintenance was proposed and finalized during rulemaking for CY 1998 PFS (62 FR 33164).

We continue to investigate potential avenues for determining equipment maintenance costs across a broad range of equipment items.

Interest Rate: In the CY 2013 PFS final rule with comment period (77 FR 68902), we updated the interest rates used in developing an equipment cost per minute calculation. The interest rate was based on the Small Business Administration (SBA) maximum interest rates for different categories of loan size (equipment cost) and maturity (useful life). The interest rates are listed in Table 3. (See 77 FR 68902 for a thorough discussion of this issue.) We are not proposing any changes to these interest rates for CY 2017.

TABLE 3—SBA MAXIMUM INTEREST RATES

Price	Useful life (years)	Interest rate (%)
<$25K	<7	7.50
$25K to $50K	<7	6.50
>$50K	<7	5.50
<$25K	7+	8.00
$25K to $50K	7+	7.00
>$50K	7+	6.00

d. Proposed Changes to Direct PE Inputs for Specific Services

This section focuses on specific PE inputs. The direct PE inputs are included in the CY 2017 direct PE input database, which is available on our Web site under downloads for the CY 2017 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.*

(1) PE Inputs for Digital Imaging Services

Prior to the CY 2015 PFS rulemaking cycle, the RUC provided a recommendation regarding the PE inputs for digital imaging services. Specifically, the RUC recommended that we remove supply and equipment items associated with film technology from a previously specified list of codes since these items were no longer typical resource inputs. The RUC also recommended that the Picture Archiving and Communication System (PACS) equipment be included for these imaging services since these items had been become typically used in furnishing imaging services. However, since we did not receive any invoices for the PACS system prior to that year's proposed rule, we were unable to determine the appropriate pricing to use for the inputs. For CY 2015, we finalized our proposal to remove the film supply and equipment items, and to create a new equipment item as a proxy for the PACS workstation as a direct expense (79 FR 67561–67563). We used the price associated with ED021 (computer, desktop, w-monitor) to price the new item, ED050 (PACS Workstation Proxy), pending receipt of invoices to facilitate pricing specific to the PACS workstation. Subsequent to establishing payment rates for CY 2015, we received information from several stakeholders regarding pricing for items related to the digital acquisition and storage of images. We received invoices from one stakeholder that facilitated a proposed price update for the PACS workstation in the CY 2016 PFS proposed rule, and we updated the price for the PACS workstation to $5,557 in the CY 2016 PFS final rule with comment period (80 FR 70899).

In addition to the workstation used by the clinical staff acquiring the images and furnishing the TC of the services, a stakeholder also submitted more detailed information regarding a workstation used by the practitioner interpreting the image in furnishing the PC of many of these services.

As we stated in the CY 2015 PFS final rule with comment period (79 FR 67563), we generally believe that workstations used by these practitioners are more accurately considered indirect costs associated with the PC of the service. However, we understand that the professional workstations for interpretation of digital images are similar in principle to some of the previous film inputs incorporated into the global and technical components of the codes, such as the view box equipment. Given that the majority of these services are reported globally in the nonfacility setting, we believe it is appropriate to include these costs as direct inputs for the associated HCPCS codes. Based on our established methodology in which single codes with professional and technical components are constructed by assigning work RVUs exclusively to the professional component and direct PE inputs exclusively to the technical components, these costs would be incorporated into the PE RVUs of the global and technical component of the HCPCS code.

We stated in the CY 2016 PFS final rule with comment period that the costs of the professional workstation may be analogous to costs related to the use of film previously incorporated as direct PE inputs for these services. We also solicited comments on whether including the professional workstation as a direct PE input for these codes would be appropriate, given that the resulting PE RVUs would be assigned to the global and technical components of the codes. Commenters responded by indicating their approval of the concept of a professional PACS workstation used for interpretation of digital images. We received invoices for the pricing of a professional PACS workstation, as well as additional invoices for the pricing of a mammography-specific version of the professional PACS workstation. The RUC also included these new equipment items in its recommendations for the CY 2017 PFS rulemaking cycle.

Based on our analysis of submitted invoices, we are proposing to price the professional PACS workstation (ED053) at $14,616.93. We are not proposing a change in price for the current technical PACS workstation (ED050), which will remain at a price of $5,557.00.

The price of the professional PACS workstation is based upon individual invoices submitted for the cost of a PC Tower ($1531.52), a pair of 3 MP monitors ($10,500.00 in total), a keyboard and mouse ($84.95), a UPS power backup devices for TNP ($1098.00), and a switch for PACS monitors/workstations ($1402.46).

We are proposing to add the professional PACS workstation to many CPT codes in the 70000 series that use the current technical PACS workstation (ED050) and include professional work for which such a workstation would be used. We are not proposing to add the equipment item to add-on codes since the base codes would include minutes for the item. We are also not proposing to add the item to codes that are therapeutic in nature, as the professional PACS workstation is intended for use in diagnostic services. We are therefore not proposing to add the item to codes in the Radiation Therapy section (77261 through 77799) or the Nuclear Medicine Cardiology section (78414–78499). We also are not proposing to add the item to image guidance codes where the dominant provider is not a radiologist (77002, 77011, 77071, 77077, and 77081) according to the most recent year of claims data, since we believe a single workstation would be more typical in those cases. We have identified approximately 426 codes to which we are proposing to add a professional PACS workstation. Please see Table 4 for the full list of affected codes.

For the professional PACS workstation, we are proposing to assign equipment time equal to the intraservice work time plus half of the preservice work time associated with the codes, since the work time generally reflects the time associated with the professional interpretation. We are proposing half of the preservice work time for the professional PACS workstation, as we do not believe that the practitioner would typically spend all of the preservice work period using the equipment. For older codes that do not have a breakdown of physician work time by service period, and only have an overall physician work time, we are proposing to use half the total work time as an approximation of the intraservice work time plus one half of the preservice work time. In our review of services that contained an existing PACS workstation and had a breakdown of physician work time, we found that half of the total time was a reasonable approximation for the value of intraservice work time plus one half of preservice work time where no such breakdown existed. We also considered using an equipment time formula of the physician intraservice time plus 1 minute (as a stand-in for the physician preservice work time). We are seeking public comment on the most accurate equipment time formula for the professional PACS workstation.

We are seeking public comment on the proposed list of codes that would incorporate either the professional PACS workstation. We are interested in public comment on the codes for which a professional PACS workstation should be included, and whether one of these professional workstations should be included for codes outside the 70000 series. In cases within the 70000 series where radiologists are not the typical specialty reporting the code, such as CPT codes 77002 and 77011, we are asking whether it would be appropriate to add one of the professional PACS workstations to these services.

TABLE 4—CODES WITH PROFESSIONAL PACS WORKSTATION IN THE PROPOSED DIRECT PE INPUT DATABASE

HCPCS	ED053 minutes
70015	12
70030	3
70100	3
70110	4
70120	3
70130	4
70134	4
70140	3
70150	4
70160	3
70190	3
70200	4
70210	3
70220	4
70240	3
70250	4
70260	7
70300	2
70310	3
70320	3
70328	3
70330	22
70332	6
70336	20
70350	3
70355	5
70360	3
70370	4
70371	9
70380	3
70390	5
70450	12
70460	15
70470	18
70480	13
70481	13
70482	14
70490	13
70491	13
70492	14
70540	14
70542	19
70543	19
70544	13
70545	18
70546	18
70547	13
70548	20
70549	25
70551	21
70552	23
70553	28
70554	43
71010	4
71015	3

TABLE 4—CODES WITH PROFESSIONAL PACS WORKSTATION IN THE PROPOSED DIRECT PE INPUT DATABASE—Continued

HCPCS	ED053 minutes
71020	4
71021	4
71022	4
71023	5
71030	4
71034	5
71035	3
71100	5
71101	4
71110	4
71111	5
71120	3
71130	3
71250	18
71260	17
71270	13
71275	28
71550	15
71551	30
71552	28
71555	33
72020	3
72040	4
72050	6
72052	6
72070	4
72072	3
72074	3
72080	3
72081	6
72082	7
72083	8
72084	9
72100	4
72110	6
72114	6
72120	4
72125	18
72126	12
72127	12
72128	18
72129	12
72130	12
72131	18
72132	12
72133	12
72141	23
72142	26
72146	23
72147	26
72148	23
72149	26
72156	28
72157	28
72158	28
72159	31
72170	5
72190	3
72191	28
72192	12
72193	12
72194	12
72195	30
72196	26
72197	30
72198	28
72200	3
72202	3
72220	3
72240	19
72255	18
72265	18
72270	23
72275	36
72285	9
72295	9
73000	3
73010	3
73020	3
73030	5
73040	6
73050	3
73060	4
73070	3
73080	4
73085	6
73090	3
73092	3
73100	4
73110	4
73115	6
73120	4
73130	4
73140	3
73200	18
73201	11
73202	12
73206	35
73218	25
73219	25
73220	30
73221	23
73222	23
73223	35
73225	31
73501	4
73502	5
73503	6
73521	5
73522	6
73523	7
73525	6
73551	4
73552	5
73560	4
73564	6
73565	4
73580	6
73590	4
73592	3
73600	4
73610	4
73615	6
73620	4
73630	4
73650	3
73660	3
73700	18
73701	11
73702	12
73706	35
73718	20
73719	25
73720	30
73721	23
73722	24
73723	32
73725	33
74000	4
74010	3
74020	4
74022	4
74150	14
74160	17
74170	21
74174	33
74175	28
74176	25
74177	28
74178	33
74181	15
74182	28
74183	35
74185	33
74210	5
74220	5
74230	12
74240	7
74241	7
74245	9
74246	7
74247	18
74249	9
74250	5
74251	33
74260	6
74261	43
74262	48
74263	42
74270	7
74280	23
74283	19
74290	4
74400	18
74410	6
74415	6
74430	4
74440	5
74455	4
74485	6
74710	4
74712	68
74740	5
75557	45
75559	58
75561	50
75563	66
75571	13
75572	25
75573	38
75574	35
75600	6
75605	11
75625	11
75630	13
75635	50
75658	13
75705	20
75710	11
75716	13
75726	11

TABLE 4—CODES WITH PROFESSIONAL PACS WORKSTATION IN THE PROPOSED DIRECT PE INPUT DATABASE—Continued

HCPCS	ED053 minutes
75731	11
75733	13
75736	11
75741	13
75743	16
75746	11
75756	11
75791	33
75809	5
75820	7
75822	11
75825	11
75827	11
75831	11
75833	14
75840	11
75842	14
75860	11
75870	11
75872	11
75880	7
75885	14
75887	14
75889	11
75891	11
75893	6
75901	11
75902	13
75962	6
75966	13
75978	6
75984	8
75989	12
76000	3
76010	3
76080	6
76098	3
76100	6
76101	6
76102	6
76120	5
76376	8
76380	10
76390	28
76506	10
76536	12
76604	9
76700	14
76705	11
76770	13
76775	11
76776	13
76800	14
76801	18
76805	18
76811	35
76813	23
76815	8
76816	18
76817	13
76818	35
76819	28
76820	13
76821	13
76825	45
76826	11
76830	13
76831	30
76856	13
76857	10
76870	10
76872	20
76873	40
76881	18
76885	20
76886	15
76936	71
76942	19
76970	8
77012	11
77014	9
77021	53
77053	5
77054	5
77058	50
77059	55
77072	3
77074	5
77075	6
77076	12
77084	15
78012	8
78013	13
78014	13
78015	31
78016	49
78018	29
78070	13
78071	18
78072	23
78075	38
78102	18
78103	22
78104	20
78135	48
78140	40
78185	16
78190	40
78195	30
78201	16
78202	20
78205	20
78206	25
78215	13
78216	22
78226	13
78227	18
78230	19
78231	23
78232	28
78258	27
78261	21
78262	25
78264	13
78265	18
78266	23
78278	18
78290	18
78291	31
78300	15
78305	22
78306	11
78315	11
78320	24
78579	8
78580	13
78582	15
78597	13
78598	13
78600	16
78601	18
78605	21
78606	22
78607	29
78610	10
78630	24
78635	36
78645	32
78647	15
78650	40
78660	16
78700	17
78701	18
78707	22
78708	32
78709	40
78710	21
78740	30
78761	20
78800	28
78801	32
78802	24
78803	43
78804	35
78805	25
78806	23
78807	37
79440	24
G0389	9
767X1	13

(2) Standardization of Clinical Labor Tasks

As we noted in the CY 2015 PFS rule (79 FR 67640–67641), we continue to work on revisions to the direct PE input database to provide the number of clinical labor minutes assigned for each task for every code in the database instead of only including the number of clinical labor minutes for the preservice, service, and postservice periods for each code. In addition to increasing the transparency of the information used to set PE RVUs, this improvement would allow us to compare clinical labor times for activities associated with services across the PFS, which we believe is important to maintaining the relativity of the direct PE inputs. This information would facilitate the identification of the usual numbers of minutes for clinical labor tasks and the identification of exceptions to the usual values. It would also allow for greater transparency and consistency in the assignment of equipment minutes based on clinical labor times. Finally, we believe that the information can be useful in maintaining standard times for particular clinical labor tasks that can be applied consistently to many codes as they are valued over several years, similar in principle to the use of physician preservice time packages. We believe such standards would provide greater consistency among codes that share the same clinical labor tasks and could improve relativity of values among codes. For example, as medical practice and technologies change over time, changes in the standards could be updated at once for all codes with the applicable clinical labor tasks, instead of waiting for individual codes to be reviewed.

In the following paragraphs, we address a series of issues related to clinical labor tasks, particularly relevant to services currently being reviewed under the misvalued code initiative.

(a) Clinical Labor Tasks Associated With Digital Imaging

In the CY 2015 PFS rule, we noted that the RUC recommendation regarding inputs for digital imaging services indicated that, as each code is reviewed under the misvalued code initiative, the clinical labor tasks associated with digital technology (instead of film) would need to be addressed. When we reviewed that recommendation, we did not have the capability of assigning standard clinical labor times for the hundreds of individual codes since the direct PE input database did not previously allow for comprehensive adjustments for clinical labor times based on particular clinical labor tasks. Therefore, consistent with the recommendation, we proposed to remove film-based supply and equipment items but maintain clinical labor minutes that were assigned based on film technology.

As noted in the paragraphs above, we continue to improve the direct PE input database by specifying for each code the minutes associated with each clinical labor task. Once completed, this work would allow adjustments to be made to minutes assigned to particular clinical labor tasks related to digital technology that occur in multiple codes, consistent with the changes that were made to individual supply and equipment items. In the meantime, we believe it would be appropriate to establish standard times for clinical labor tasks associated with all digital imaging services for purposes of reviewing individual services at present, and for possible broad-based standardization once the changes to the direct PE input database facilitate our ability to adjust time across services. During the CY 2016 PFS rulemaking cycle, we proposed appropriate standard minutes for five different clinical labor tasks associated with services that use digital imaging technology. In the CY 2016 PFS final rule with comment period (80 FR 70901), we finalized appropriate standard minutes for four of those five activities, which are listed in Table 5.

TABLE 5—CLINICAL LABOR TASKS ASSOCIATED WITH DIGITAL IMAGING TECHNOLOGY

Clinical labor task	Typical minutes
Availability of prior images confirmed	2
Patient clinical information and questionnaire reviewed by technologist, order from physician confirmed and exam protocoled by radiologist	2
Review examination with interpreting MD	2
Exam documents scanned into PACS. Exam completed in RIS system to generate billing process and to populate images into Radiologist work queue	1

We did not finalize standard minutes for the activity “Technologist QC's images in PACS, checking for all images, reformats, and dose page.” We agreed with commenters that this task may require a variable length of time depending on the number of images to be reviewed. We stated that it may be appropriate to establish several different standard times for this clinical labor task for a low/medium/high quantity of images to be reviewed, in the same fashion that the clinical labor assigned to clean a surgical instrument package has two different standard times depending on the use of a basic pack (10 minutes) or a medium pack (30 minutes). We solicited public comment and feedback on this subject, with the anticipation of including a proposal in the CY 2017 proposed rule.

We received many comments suggesting that this clinical labor activity should not have a standard time value. Commenters stated that the number of minutes varies significantly for different imaging modalities; and the time is not simply based on the quantity of images to be reviewed, but also the complexity of the images. The commenters recommended that time for this clinical labor activity should be assigned on a code by code basis. We agree with the commenters that the amount of clinical labor needed to check images in a PACS workstation may vary depending on the service. However, we do not believe that this precludes the possibility of establishing standards for clinical labor tasks as we have done in the past by creating multiple standard times, for example, those assigned to cleaning different kinds of scopes. We continue to believe that the use of clinical labor standards provides greater consistency among codes that share the same clinical labor tasks and can improve relativity of values among codes. We are proposing to establish a range of appropriate standard minutes for the clinical labor activity Technologist QCs images in PACS, checking for all images, reformats, and dose page. These standard minutes will be applied to new and revised codes that make use of this clinical labor activity when they are reviewed by us for valuation. We are proposing 2 minutes as the standard for the simple case, 3 minutes as the standard for the intermediate case, and 4 minutes as the standard for the complex case. We are proposing the simple case of 2 minutes as the standard for the typical procedure code involving routine use of imaging. These values are based upon a review of the existing minutes assigned for this clinical labor activity; we have determined that 2 minutes is the duration for most services and a small number of codes with more complex forms of digital imaging have higher values. We are proposing to use 2 minutes for services involving routine x-rays (simple), 3 minutes for services involving CTs and MRIs (intermediate), and 4 minutes for the most highly complex services which would exceed these more typical cases. We are soliciting comments regarding the most accurate category—simple, intermediate, or complex for existing codes, and in particular what criteria might be used to identify complex cases systematically.

(b) Pathology Clinical Labor Tasks

As with the clinical labor tasks associated with digital imaging, many of the currently assigned times for the specialized clinical labor tasks associated with pathology services are not consistent across codes. In reviewing past RUC recommendations for pathology services, we have not identified information that supports the judgment that the same tasks take significantly more or less time depending on the individual service for which they are performed, especially given the high degree of specificity with which the tasks are described. We continue to believe that, in general, a clinical labor task will tend to take the same amount of time to perform as the same clinical labor task when it is performed in a clinically similar service.

Therefore, we developed standard times for clinical labor tasks that we have used in finalizing direct PE inputs in recent years, starting in the CY 2012 PFS final rule with comment period (76 FR 73213). These times were based on our review and assessment of the current times included for these clinical labor tasks in the direct PE input database. We proposed in the CY 2016 PFS proposed rule to establish standard times for a list of 17 clinical labor tasks related to pathology services, and solicited public feedback regarding our proposed standards. Many commenters stated in response to our proposal that they did not support the standardization of clinical labor activities across pathology services. Commenters stated that establishing a single standard time for each clinical labor task was infeasible due to the differences in batch size or number of blocks across different pathology procedures. Several commenters indicated that it might be possible to standardize across codes with the same batch sizes, and urged us to consider pathology-specific details, such as batch size and block number, in the creation of any future standard times for clinical labor tasks related to pathology services.

As we stated in the CY 2016 PFS proposed rule, we developed the proposed standard times based on our review and assessment of the current times included for these clinical labor tasks in the direct PE input database. We believe that, generally speaking, clinical labor tasks with the same description are comparable across different pathology procedures. We believe this to be true based on the comparability of clinical labor tasks in non-pathology services, as well as the high degree of specificity with which most pathology tasks are described relative to clinical labor tasks associated with other PFS services. We concurred with commenters that accurate clinical labor times for pathology codes may be dependent on the number of blocks or batch size typically used for each individual service. However, we also believe that it is appropriate and feasible to establish "per block" standards or standards varied by batch size assumptions for many clinical labor activities that would be comparable across a wide range of individual services. We have received detailed information regarding batch size and number of blocks during review of individual pathology services on an intermittent basis in the past. We requested regular submission of these details on the PE worksheets supplied by the RUC as part of the review process for pathology services, as a means to assist in the determination of the most accurate direct PE inputs.

We also stated our belief that many of the clinical labor activities for which we proposed to establish standard times were tasks that do not depend on number of blocks or batch size. Clinical labor activities such as "Clean room/equipment following procedure" and "Dispose of remaining specimens" would typically remain standard across different services without varying by block number or batch size, with the understanding that additional time may be required above the standard value for a clinical labor task that is part of an unusually complex or difficult service. As a result, we ultimately finalized standard times for 6 of the 17 proposed clinical labor activities in the CY 2016 final rule with comment period (80 FR 70902). We have listed the finalized standard times in Table 6. We are currently proposing no further action on the remaining 11 clinical labor activities pending further action by the RUC (see below).

TABLE 6—STANDARD TIMES FOR CLINICAL LABOR TASKS ASSOCIATED WITH PATHOLOGY SERVICES

Clinical labor task	Standard clinical labor time (minutes)
Accession specimen/prepare for examination	4
Assemble and deliver slides with paperwork to pathologists	0.5
Assemble other light microscopy slides, open nerve biopsy slides, and clinical history, and present to pathologist to prepare clinical pathologic interpretation	0.5
Clean room/equipment following procedure (including any equipment maintenance that must be done after the procedure)	1
Dispose of remaining specimens, spent chemicals/other consumables, and hazardous waste	1
Prepare, pack and transport specimens and records for in-house storage and external storage (where applicable)	1

We remain committed to the process of establishing standard clinical labor times for tasks associated with pathology services. This may include establishing standards on a per-block or per-batch basis, as we indicated during the previous rulemaking cycle. However, we are aware that the PE Subcommittee of the RUC is currently working to standardize the pathology clinical labor activities they use in making their recommendations. We believe the RUC's efforts to narrow the current list of several hundred pathology clinical labor tasks to a more manageable number through the consolidation of duplicative or highly similar activities into a single description may serve PFS relativity and facilitate greater transparency in PFS ratesetting. We also believe that the RUC's standardization of pathology clinical labor tasks would facilitate our capacity to establish standard times for pathology clinical labor tasks in future rulemaking. Therefore, we are not proposing any additional change to clinical labor tasks associated with pathology services at this time.

(3) Equipment Recommendations for Scope Systems

During our routine reviews of direct PE input recommendations, we have regularly found unexplained inconsistencies involving the use of scopes and the video systems associated with them. Some of the scopes include video systems bundled into the equipment item, some of them include scope accessories as part of their price, and some of them are standalone scopes with no other equipment included. It is not always clear which equipment items related to scopes fall into which of these categories. We have also frequently found anomalies in the equipment recommendations, with equipment items that consist of a scope and video system bundle recommended along with a separate scope video system. Based on our review, the variations do not appear to be consistent with the different code descriptions.

To promote appropriate relativity among the services and facilitate the transparency of our review process, during review of recommended direct PE inputs for the CY 2017 PFS proposed rule, we developed a structure that separates the scope and the associated video system as distinct equipment items for each code. Under this approach, we are proposing standalone prices for each scope, and separate prices for the video systems that are used with scopes. We would define the scope video system as including: (1) A monitor; (2) a processor; (3) a form of digital capture; (4) a cart; and (5) a printer. We believe that these equipment components represent the typical case for a scope video system. Our model for this system is the "video system, endoscopy (processor, digital capture, monitor, printer, cart)" equipment item (ES031), which we are proposing to re-price as part of this separate pricing approach. We obtained current pricing invoices for the endoscopy video system as part of our investigation of these issues involving scopes, which we are proposing to use for this re-pricing. We understand that there may be other accessories associated with the use of scopes; we are proposing to separately price any scope accessories, and individually evaluate their inclusion or exclusion as direct PE inputs for particular codes as usual under our current policy based on whether they are typically used in furnishing the services described by the particular codes.

We are also proposing standardizing refinements to the way scopes have been defined in the direct PE input database. We believe that there are four general types of scopes: Non-video scopes; flexible scopes; semi-rigid scopes, and rigid scopes. Flexible scopes, semi-rigid scopes, and rigid scopes would typically be paired with one of the video scope systems, while the non-video scopes would not. The flexible scopes can be further divided into diagnostic (or non-channeled) and therapeutic (or channeled) scopes. We are proposing to identify for each anatomical application: (1) A rigid scope; (2) a semi-rigid scope; (3) a non-video flexible scope; (4) a non-channeled flexible video scope; and (5) a channeled flexible video scope. We are proposing to classify the existing scopes in our direct PE database under this classification system, to improve the transparency of our review process and improve appropriate relativity among the services. We plan to propose input prices for these equipment items through future rulemaking.

We have proposed these changes only for the reviewed codes that make use of scopes; this applies to the codes in the Flexible Laryngoscopy family (CPT codes 31575, 31576, 31577, 31578, 315X1, 315X2, 315X3, 31579) (see section II.L) and the Laryngoplasty family (CPT codes 31580, 31584, 31587, 315Y1, 315Y2, 315Y3, 315Y4, 315Y5, 315Y6) (see section II.L) along with updated prices for the equipment items related to scopes utilized by these services. We are also soliciting comment on this separate pricing structure for scopes, scope video systems, and scope accessories, which we could consider proposing to apply to other PFS codes in future rulemaking.

(4) Technical Corrections to Direct PE Input Database

Subsequent to the publication of the CY 2016 PFS final rule with comment period, stakeholders alerted us to several clerical inconsistencies in the direct PE database. We propose to correct these inconsistencies as described below and reflected in the CY 2017 direct PE input database displayed on our Web site under downloads for the CY 2017 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.*

For CY 2017, we are proposing the following technical corrections:

- For CPT codes 72081–72084, a stakeholder informed us that the equipment time for the PACS workstation (ED050) should be equal to the clinical labor during the service period; the equipment time formula we used for these codes for CY 2016 erroneously included 4 minutes of preservice clinical labor. We agree with the stakeholder that the PACS workstation should use the standard equipment time formula for a PACS workstation for these codes. As a result, we are proposing to refine the ED050 equipment time to 21 minutes for CPT code 72081, 36 minutes for CPT code 72082, 44 minutes for CPT code 72083, and 53 minutes for CPT code 72084 to reflect the clinical labor time associated with these codes. This same commenter also indicated that a number of clinical labor activities had been entered in the database in the incorrect service period for CPT codes 37215, 50432, 50694, and 72081. These clinical labor activities were incorrectly listed in the "postservice" period instead of the "service post" period. We are proposing to make these technical corrections as well so that the minutes are assigned to the appropriate service period within the direct PE input database.
- Another stakeholder alerted us that Ileoscopy codes 44380, 44381 and 44382 did not include the direct PE input equipment item called the Gomco suction machine (EQ235) and indicated that this omission appeared to be inadvertent. We agree that it was. We have included the item EQ235 in the proposed direct PE input database for CPT code 44380 at a time of 29 minutes, for CPT code 44381 at a time of 39 minutes, and to CPT code 44382 at a time of 34 minutes.

The PE RVUs displayed in Addendum B on our Web site were calculated with the inputs displayed in the CY 2017 direct PE input database.

(5) Restoration of Inputs

Several of the PE worksheets included in the RUC recommendations for CY 2016 contained time for the equipment item "xenon light source" (EQ167). Because there appeared to be two special light sources already present (the fiberoptic headlight and the endoscope itself) in the services for which this equipment item was recommended by the RUC, we believed that the use of only one of these light sources would be typical and removed the xenon light equipment time. In the CY 2016 PFS final rule with comment period, we restored the xenon light (EQ167) and removed the fiberoptic headlight (EQ170) with the same number of equipment minutes for CPT codes 30300, 31295, 31296, 31297, and 92511.

We received comments expressing approval for the restoration of the xenon light. However, the commenters also stated that the two light sources were not duplicative, but rather, both a headlight and a xenon light source are required concurrently for otolaryngology procedures when scopes are utilized. The commenters requested that the fiberoptic headlight be restored to these codes.

We agree with the commenters that the use of both light sources would be typical for these procedures. We are therefore proposing to add the fiberoptic headlight (EQ170) to CPT codes 30300, 31295, 31296, 31297, and 92511 at the same number of equipment minutes as the xenon light (EQ167).

(6) Updates to Prices for Existing Direct PE Inputs

In the CY 2011 PFS final rule with comment period (75 FR 73205), we finalized a process to act on public requests to update equipment and supply price and equipment useful life inputs through annual rulemaking beginning with the CY 2012 PFS proposed rule. For CY 2017, we are proposing the following price updates for existing direct PE inputs:

Several commenters wrote to discuss the price of the Antibody Estrogen Receptor monoclonal (SL493). We received information including three invoices with new pricing information regarding the SL493 supply. We are proposing to use this information to propose for the supply item SL493 a price of $14.00 per test, which is the average price based on the invoices that we received in total for the item.

We are also proposing to update the price for two supplies in response to the submission of new invoices. The proposed price for ''antigen, venom'' supply (SH009) reflects an increase from $16.67 to $20.14 per milliliter, and the proposed price for ''antigen, venom, tri-vespid'' supply (SH010) reflects an increase from $30.22 to $44.05 per milliliter.

We routinely accept public submission of invoices as part of our process for developing payment rates for new, revised, and potentially misvalued codes. Often these invoices are submitted in conjunction with the RUC recommended values for the codes. For CY 2017, we note that some stakeholders have submitted invoices for new, revised, or potentially misvalued codes since the February deadline established for code valuation recommendations. To be included a given year's proposed rule, we generally need to receive invoices by the same February deadline. Of course, we will consider invoices submitted as public comments during the comment period following the publication of the proposed rule, and will consider any invoices received after February and/or outside of the public comment process as part of our established annual process for requests to update supply and equipment prices.

B. Determination of Malpractice Relative Value Units (RVUs)

1. Overview

Section 1848(c) of the Act requires that each service paid under the PFS be composed of three components: Work, PE, and malpractice expense (MP). As required by section 1848(c)(2)(C)(iii) of the Act, beginning in CY 2000, MP RVUs are resource based. Malpractice RVUs for new codes after 1991 were extrapolated from similar existing codes or as a percentage of the corresponding work RVU. Section 1848(c)(2)(B)(i) of the Act also requires that we review, and if necessary adjust, RVUs no less often than every 5 years. In the CY 2015 PFS final rule with comment period, we implemented the third review and update of MP RVUs. For a comprehensive discussion of the third review and update of MP RVUs see the CY 2015 proposed rule (79 FR 40349 through 40355) and final rule with comment period (79 FR 67591 through 67596).

To determine MP RVUs for individual PFS services, our MP methodology uses three primary kinds of data: Specialty-level risk factors based on the collection of specialty-specific MP premium data that represent the actual expense incurred by practitioners to obtain MP insurance; Medicare claims data to determine service level risk factors based on a weighted average risk factors of the specialties that furnish each service, and the higher of the work RVU or clinical labor RVU to adjust the service level risk factor for the intensity and complexity of the service. Prior to CY 2016, MP RVUs were only updated once every 5 years, except in the case of new and revised codes.

As explained in the CY 2011 PFS final rule with comment period (75 FR 73208), MP RVUs for new and revised codes effective before the next 5-year review of MP RVUs were determined either by a direct crosswalk from a similar source code or by a modified crosswalk to account for differences in work RVUs between the new/revised code and the source code. For the modified crosswalk approach, we adjust (or scale) the MP RVU for the new/revised code to reflect the difference in work RVU between the source code and the new/revised work RVU (or, if greater, the difference in the clinical labor portion of the fully implemented PE RVU) for the new code. For example, if the proposed work RVU for a revised code were 10 percent higher than the work RVU for its source code, the MP RVU for the revised code would be increased by 10 percent over the source code MP RVU. Under this approach the same risk factor is applied for the new/revised code and source code, but the work RVU for the new/revised code is used to adjust the MP RVUs for risk.

In the CY 2016 PFS final rule with comment period (80 FR 70906 through 70910), we finalized a policy to begin conducting annual MP RVU updates to reflect changes in the mix of practitioners providing services (using Medicare claims data), and to adjust MP RVUs for risk for intensity and complexity (using the work RVU or clinical labor RVU). We also finalized a policy to modify the specialty mix assignment methodology (for both MP and PE RVU calculations) to use an average of the 3 most recent years of data instead of a single year of data. We stated that under this approach, the specialty-specific risk factors would continue to be updated through notice and comment rulemaking every 5 years using updated premium data, but would remain unchanged between the 5-year reviews.

For CY 2016, we did not propose to discontinue our current approach for determining MP RVUs for new/revised codes. For the new and revised codes for which we proposed work RVUs and PE inputs, we also published the proposed MP crosswalks used to determine their MP RVUs. We address comments regarding valuation of new and revised codes in section II.L of this proposed rule, which makes clear the codes with interim final values for CY 2016 have newly proposed values for CY 2017, all of which are again open for comment. The MP crosswalks for new and revised codes with interim final values were established in the CY 2016 PFS final rule with comment period; we will respond to comments regarding these interim final values in the CY 2017 PFS final rule.

2. Updating Specialty Specific Risk Factors

The proposed CY 2017 GPCI update (eighth update), discussed in section II.E of this proposed rule, reflects updated MP premium data, collected for the purpose of proposing updates to the MP GPCIs. While we could use the updated MP premium data obtained for the purposes of the proposed eighth GPCI update to propose updates to the specialty risk factors used in the calculation of MP RVUs, this would not be consistent with the policy we previously finalized in the CY 2016 PFS final rule with comment period. In that rule, we indicated that the specialty-specific risk factors would continue to be updated through notice and comment rulemaking every 5 years using updated premium data, but would remain unchanged between the 5-year reviews. Additionally, consistent with the statutory requirement at section 1848(e)(1)(C) of the Act, only $1/2$ of the adjustment to MP GPCIs would be applied for CY 2017 based on the new

MP premium data. As such, we do not think it would be appropriate to propose to update the specialty risk factors for CY 2017 based on the updated MP premium data that is reflected in the proposed CY 2017 GPCI update. Therefore, we are not currently proposing to update the specialty-risk factors based on the new premium data collected for the purposes of the 3-year GPCI update for CY 2017 at this time. However, we seek comment on whether we should consider doing so, perhaps as early as for 2018, prior to the fourth review and update of MP RVUs that must occur no later than CY 2020.

C. Medicare Telehealth Services

1. Billing and Payment for Telehealth Services

Several conditions must be met for Medicare to make payments for telehealth services under the PFS. The service must be on the list of Medicare telehealth services and meet all of the following additional requirements:

- The service must be furnished via an interactive telecommunications system.
- The service must be furnished by a physician or other authorized practitioner.
- The service must be furnished to an eligible telehealth individual.
- The individual receiving the service must be located in a telehealth originating site.

When all of these conditions are met, Medicare pays a facility fee to the originating site and makes a separate payment to the distant site practitioner furnishing the service.

Section 1834(m)(4)(F)(i) of the Act defines Medicare telehealth services to include consultations, office visits, office psychiatry services, and any additional service specified by the Secretary, when furnished via a telecommunications system. We first implemented this statutory provision, which was effective October 1, 2001, in the CY 2002 PFS final rule with comment period (66 FR 55246). We established a process for annual updates to the list of Medicare telehealth services as required by section 1834(m)(4)(F)(ii) of the Act in the CY 2003 PFS final rule with comment period (67 FR 79988).

As specified at § 410.78(b), we generally require that a telehealth service be furnished via an interactive telecommunications system. Under § 410.78(a)(3), an interactive telecommunications system is defined as multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner.

Telephones, facsimile machines, and stand-alone electronic mail systems do not meet the definition of an interactive telecommunications system. An interactive telecommunications system is generally required as a condition of payment; however, section 1834(m)(1) of the Act allows the use of asynchronous "store-and-forward" technology when the originating site is part of a federal telemedicine demonstration program in Alaska or Hawaii. As specified in § 410.78(a)(1), asynchronous store-and-forward is the transmission of medical information from an originating site for review by the distant site physician or practitioner at a later time.

Medicare telehealth services may be furnished to an eligible telehealth individual notwithstanding the fact that the practitioner furnishing the telehealth service is not at the same location as the beneficiary. An eligible telehealth individual is an individual enrolled under Part B who receives a telehealth service furnished at a telehealth originating site.

Practitioners furnishing Medicare telehealth services are reminded that these services are subject to the same non-discrimination laws as other services, including the effective communication requirements for persons with disabilities of section 504 of the Rehabilitation Act and language access for persons with limited English proficiency, as required under Title VI of the Civil Rights Act of 1964. For more information, see *http://www.hhs.gov/ocr/civilrights/resources/specialtopics/hospitalcommunication.*

Practitioners furnishing Medicare telehealth services submit claims for telehealth services to the MACs that process claims for the service area where their distant site is located. Section 1834(m)(2)(A) of the Act requires that a practitioner who furnishes a telehealth service to an eligible telehealth individual be paid an amount equal to the amount that the practitioner would have been paid if the service had been furnished without the use of a telecommunications system.

Originating sites, which can be one of several types of sites specified in the statute where an eligible telehealth individual is located at the time the service is being furnished via a telecommunications system, are paid a facility fee under the PFS for each Medicare telehealth service. The statute specifies both the types of entities that can serve as originating sites and the geographic qualifications for originating sites. With regard to geographic qualifications, § 410.78(b)(4) limits originating sites to those located in rural health professional shortage areas (HPSAs) or in a county that is not included in a metropolitan statistical area (MSA).

Historically, we have defined rural HPSAs to be those located outside of MSAs. Effective January 1, 2014, we modified the regulations regarding originating sites to define rural HPSAs as those located in rural census tracts as determined by the Office of Federal Rural Health Policy (FORHP) of the Health Resources and Services Administration (HRSA) (78 FR 74811). Defining "rural" to include geographic areas located in rural census tracts within MSAs allows for broader inclusion of sites within HPSAs as telehealth originating sites. Adopting the more precise definition of "rural" for this purpose expands access to health care services for Medicare beneficiaries located in rural areas. HRSA has developed a Web site tool to provide assistance to potential originating sites to determine their geographic status. To access this tool, see the CMS Web site at *https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/index.html.*

An entity participating in a federal telemedicine demonstration project that has been approved by, or received funding from, the Secretary as of December 31, 2000 is eligible to be an originating site regardless of its geographic location.

Effective January 1, 2014, we also changed our policy so that geographic status for an originating site would be established and maintained on an annual basis, consistent with other telehealth payment policies (78 FR 74400). Geographic status for Medicare telehealth originating sites for each calendar year is now based upon the status of the area as of December 31 of the prior calendar year.

For a detailed history of telehealth payment policy, see 78 FR 74399.

2. Adding Services to the List of Medicare Telehealth Services

As noted previously, in the December 31, 2002 **Federal Register** (67 FR 79988), we established a process for adding services to or deleting services from the list of Medicare telehealth services. This process provides the public with an ongoing opportunity to submit requests for adding services. Under this process, we assign any qualifying request to make additions to the list of telehealth services to one of two categories. Revisions to criteria that we use to review requests in the second category were finalized in the November 28, 2011 **Federal Register** (76 FR 73102). The two categories are:

- *Category 1:* Services that are similar to professional consultations, office visits, and office psychiatry services that are currently on the list of telehealth services. In reviewing these requests, we look for similarities between the requested and existing telehealth services for the roles of, and interactions among, the beneficiary, the physician (or other practitioner) at the distant site and, if necessary, the telepresenter, a practitioner who is present with the beneficiary in the originating site. We also look for similarities in the telecommunications system used to deliver the proposed service; for example, the use of interactive audio and video equipment.
- *Category 2:* Services that are not similar to the current list of telehealth services. Our review of these requests includes an assessment of whether the service is accurately described by the corresponding code when furnished via telehealth and whether the use of a telecommunications system to deliver the service produces demonstrated clinical benefit to the patient. Submitted evidence should include both a description of relevant clinical studies that demonstrate the service furnished by telehealth to a Medicare beneficiary improves the diagnosis or treatment of an illness or injury or improves the functioning of a malformed body part, including dates and findings, and a list and copies of published peer reviewed articles relevant to the service when furnished via telehealth. Our evidentiary standard of clinical benefit does not include minor or incidental benefits.

Some examples of clinical benefit include the following:

- Ability to diagnose a medical condition in a patient population without access to clinically appropriate in-person diagnostic services.
- Treatment option for a patient population without access to clinically appropriate in-person treatment options.
- Reduced rate of complications.
- Decreased rate of subsequent diagnostic or therapeutic interventions (for example, due to reduced rate of recurrence of the disease process).
- Decreased number of future hospitalizations or physician visits.
- More rapid beneficial resolution of the disease process treatment.
- Decreased pain, bleeding, or other quantifiable symptom.
- Reduced recovery time.

For the list of telehealth services, see the CMS Web site at *https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/index.html.*

Requests to add services to the list of Medicare telehealth services must be submitted and received no later than December 31 of each calendar year to be considered for the next rulemaking cycle. For example, qualifying requests submitted before the end of CY 2016 will be considered for the CY 2018 proposed rule. Each request to add a service to the list of Medicare telehealth services must include any supporting documentation the requester wishes us to consider as we review the request. Because we use the annual PFS rulemaking process as a vehicle for making changes to the list of Medicare telehealth services, requesters should be advised that any information submitted is subject to public disclosure for this purpose. For more information on submitting a request for an addition to the list of Medicare telehealth services, including where to mail these requests, see the CMS Web site at *https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/index.html.*

3. Submitted Requests To Add Services to the List of Telehealth Services for CY 2017

Under our existing policy, we add services to the telehealth list on a category 1 basis when we determine that they are similar to services on the existing telehealth list for the roles of, and interactions among, the beneficiary, physician (or other practitioner) at the distant site and, if necessary, the telepresenter. As we stated in the CY 2012 final rule with comment period (76 FR 73098), we believe that the category 1 criteria not only streamline our review process for publicly requested services that fall into this category, but also expedite our ability to identify codes for the telehealth list that resemble those services already on this list.

We received several requests in CY 2015 to add various services as Medicare telehealth services effective for CY 2017. The following presents a discussion of these requests, and our proposals for additions to the CY 2017 telehealth list. Of the requests received, we found that four services were sufficiently similar to ESRD-related services currently on the telehealth list to qualify on a category 1 basis. Therefore, we propose to add the following services to the telehealth list on a category 1 basis for CY 2017:

- CPT codes 90967 (End-stage renal disease (ESRD) related services for dialysis less than a full month of service, per day; for patients younger than 2 years of age; 90968 (End-stage renal disease (ESRD) related services for dialysis less than a full month of service, per day; for patients 2–11 years of age; 90969 (End-stage renal disease (ESRD) related services for dialysis less than a full month of service, per day; for patients 12–19 years of age); and 90970 (End-stage renal disease (ESRD) related services for dialysis less than a full month of service, per day; for patients 20 years of age and older).

As we indicated in the CY 2015 final rule (80 FR 41783) for the ESRD-related services (CPT codes 90963–90966) added to the telehealth list for CY 2016, the required clinical examination of the catheter access site must be furnished face-to-face "hands on" (without the use of an interactive telecommunications system) by a physician, CNS, NP, or PA. This requirement also applies to CPT codes 90967–90970.

While we did not receive a specific request, we also propose to add two advance care planning services to the telehealth list. We have determined that these services are similar to the annual wellness visits (HCPCS codes G0438 & G0439) currently on the telehealth list:

- CPT codes 99497 (advance care planning including the explanation and discussion of advance directives such as standard forms (with completion of such forms, when performed), by the physician or other qualified health care professional; first 30 minutes, face-to-face with the patient, family member(s), or surrogate); and 99498 (advance care planning including the explanation and discussion of advance directives such as standard forms (with completion of such forms, when performed), by the physician or other qualified health care professional; each additional 30 minutes (list separately in addition to code for primary procedure)).

We also received requests to add services to the telehealth list that do not meet our criteria for Medicare telehealth services. We are not proposing to add the following procedures for the reasons noted:

a. Observation Care: CPT codes—

- 99217 (observation care discharge day management (this code is to be utilized to report all services provided to a patient on discharge from "observation status" if the discharge is on other than the initial date of "observation status." To report services to a patient designated as "observation status" or "inpatient status" and discharged on the same date, use the codes for observation or inpatient care services [including admission and discharge services, 99234–99236 as appropriate.]));
- 99218 (initial observation care, per day, for the evaluation and management

of a patient which requires these three key components: A detailed or comprehensive history; a detailed or comprehensive examination; and medical decision making that is straightforward or of low complexity. Counseling and coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and family's needs. Usually, the problem(s) requiring admission to "observation status" are of low severity. Typically, 30 minutes are spent at the bedside and on the patient's hospital floor or unit);

- 99219 (initial observation care, per day, for the evaluation and management of a patient, which requires these three key components: A comprehensive history; a comprehensive examination; and medical decision making of moderate complexity. Counseling and coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and family's needs. Usually, the problem(s) requiring admission to "observation status" are of moderate severity. Typically, 50 minutes are spent at the bedside and on the patient's hospital floor or unit);
- 99220 (initial observation care, per day, for the evaluation and management of a patient, which requires these three key components: A comprehensive history; a comprehensive examination; and medical decision making of high complexity. Counseling and coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and family's needs. Usually, the problem(s) requiring admission to "observation status" are of high severity. Typically, 70 minutes are spent at the bedside and on the patient's hospital floor or unit);
- 99224 (subsequent observation care, per day, for the evaluation and management of a patient, which requires at least two of these three key components: Problem focused interval history; problem focused examination; medical decision making that is straightforward or of low complexity. Counseling and coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and family's needs. Usually, the patient is stable, recovering, or improving. Typically, 15 minutes are spent at the bedside and on the patient's hospital floor or unit);
- 99225 (subsequent observation care, per day, for the evaluation and management of a patient, which requires at least two of these three key components: An expanded problem focused interval history; an expanded problem focused examination; medical decision making of moderate complexity. Counseling and coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and family's needs. Usually, the patient is responding inadequately to therapy or has developed a minor complication. Typically, 25 minutes are spent at the bedside and on the patient's hospital floor or unit);
- 99226 (subsequent observation care, per day, for the evaluation and management of a patient, which requires at least two of these three key components: A detailed interval history; a detailed examination; medical decision making of high complexity. Counseling and coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and family's needs. Usually, the patient is unstable or has developed a significant complication or a significant new problem. Typically, 35 minutes are spent at the bedside and on the patient's hospital floor or unit);
- 99234 (observation or inpatient hospital care, for the evaluation and management of a patient including admission and discharge on the same date, which requires these three key components: A detailed or comprehensive history; a detailed or comprehensive examination; and medical decision making that is straightforward or of low complexity. Counseling and coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and family's needs. Usually the presenting problem(s) requiring admission are of low severity. Typically, 40 minutes are spent at the bedside and on the patient's hospital floor or unit);
- 99235 (observation or inpatient hospital care, for the evaluation and management of a patient including admission and discharge on the same date, which requires these three key components: A comprehensive history; a comprehensive examination; and medical decision making of moderate complexity. Counseling and coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and family's needs. Usually the presenting problem(s) requiring admission are of moderate severity. Typically, 50 minutes are spent at the bedside and on the patient's hospital floor or unit);
- 99236 (observation or inpatient hospital care, for the evaluation and management of a patient including admission and discharge on the same date, which requires these three key components: A comprehensive history; a comprehensive examination; and medical decision making of high complexity. Counseling and coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and family's needs. Usually the presenting problem(s) requiring admission are of high severity. Typically, 55 minutes are spent at the bedside and on the patient's hospital floor or unit);

The request to add these observation services referenced various studies supporting the use of observation units. The studies indicated that observation units provide safe, cost effective care to patients that need ongoing evaluation and treatment beyond the emergency department visit by having reduced hospital admissions, shorter lengths of stay, increased safety and reduced cost. Additional studies cited indicated that observation units reduce the work load on emergency department physicians, and reduce emergency department overcrowding.

In the CY 2005 PFS proposed rule (69 FR 47510), we considered a request but did not propose to add the observation CPT codes 99217–99220 to the list of Medicare telehealth services on a category two basis for the reasons described in that rule. The most recent request did not include any information that would cause us to question the previous evaluation under the category one criterion, which has not changed, regarding the significant differences in patient acuity between these services and services on the telehealth list. (69 FR 66277) While the request included evidence of the general benefits of observation units, it did not include specific information demonstrating that the services described by these codes provided clinical benefit when furnished via telehealth, which is necessary for us to consider these codes on a category two basis. Therefore, we are not proposing to add these services to the list of approved telehealth services.

b. Emergency Department Visits: CPT Codes—

- 99281 (emergency department visit for the evaluation and management of a patient, which requires these three key components: A problem focused history; a problem focused examination; and straightforward medical decision making. Counseling and coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and family's needs. Usually, the presenting problem(s) are self-limited or minor);
- 99282 (emergency department visit for the evaluation and management of a patient, which requires these three key components: An expanded problem focused history; an expanded problem focused examination; and medical decision making of low complexity. Counseling and coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and family's needs. Usually, the presenting problem(s) are of low to moderate severity);
- 99283 (emergency department visit for the evaluation and management of a patient, which requires these three key components: An expanded problem focused history; an expanded problem focused examination; and medical decision making of moderate complexity. Counseling and coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and family's needs. Usually, the presenting problem(s) are of moderate severity);
- 99284 (emergency department visit for the evaluation and management of a patient, which requires these three key components: A detailed history; a detailed examination; and medical decision making of moderate complexity. Counseling and coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and family's needs. Usually, the presenting problem(s) are of high severity, and require urgent evaluation by the physician, or other qualified health care professionals but do not pose an immediate significant threat to life or physiologic function); and
- 99285 (emergency department visit for the evaluation and management of a patient, which requires these three key components within the constraints imposed by the urgency of the patient's clinical condition and mental status: A comprehensive history; a comprehensive examination; and medical decision making of high complexity. Counseling and coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and family's needs. Usually, the presenting problem(s) are of high severity and pose an immediate significant threat to life or physiologic function).

In the CY 2005 PFS proposed rule (69 FR 47510), we considered a request but did not propose to add the emergency department visit CPT codes 99281–99285 to the list of Medicare telehealth services for the reasons described in that rule.

The current request to add the emergency department E/M services stated that the codes are similar to outpatient visit codes (CPT codes 99201–99215) that have been on the telehealth list since CY 2002. As we noted in the CY 2005 PFS final rule, while the acuity of some patients in the emergency department might be the same as in a physician's office; we believe that, in general, more acutely ill patients are more likely to be seen in the emergency department, and that difference is part of the reason there are separate codes describing evaluation and management visits in the Emergency Department setting. The practice of emergency medicine often requires frequent and fast-paced patient reassessments, rapid physician interventions, and sometimes the continuous physician interaction with ancillary staff and consultants. This work is distinctly different from the pace, intensity, and acuity associated with visits that occur in the office or outpatient setting. Therefore, we are not proposing to add these services to the list of approved telehealth services on a category one basis.

The requester did not provide any studies supporting the clinical benefit of managing emergency department patients with telehealth which is necessary for us to consider these codes on a category two basis. Therefore, we are not proposing to add these services to the list of approved telehealth services on a category two basis.

Many requesters of additions to the telehealth list urged us to consider the potential value of telehealth for providing beneficiaries access to needed expertise. We note that if clinical guidance or advice is needed in the emergency department setting, a consultation may be requested from an appropriate source, including consultations that are currently included on the list of telehealth services.

c. Critical Care Evaluation and Management: CPT Codes—

- 99291 (critical care, evaluation and management of the critically ill or critically injured patient; first 30–74 minutes); and 99292 (critical care, evaluation and management of the critically ill or critically injured patient; each additional 30 minutes (list separately in addition to code for primary service).

We previously considered and rejected adding these codes to the list of Medicare telehealth services in the CY 2009 PFS final rule (74 FR 69744) on a category 1 basis because, due to the acuity of critically ill patients, we did not believe critical care services are similar to any services on the current list of Medicare telehealth services. In that rule, we said that critical care services must be evaluated as category 2 services. Because we considered critical care services under category 2, we needed to evaluate whether these are services for which telehealth can be an adequate substitute for a face-to-face encounter, based on the category 2 criteria at the time of that request. We had no evidence suggesting that the use of telehealth could be a reasonable surrogate for the face-to-face delivery of this type of care.

The American Telemedicine Association (ATA) submitted a new request for CY 2016 that cited several studies to support adding these services on a category 2 basis. To qualify under category 2, we would need evidence that the service furnished via telehealth is still described accurately by the requested code and produces a clinical benefit for the patient via telehealth. However, in reviewing the information provided by the ATA and a study titled, "Impact of an Intensive Care Unit Telemedicine Program on Patient Outcomes in an Integrated Health Care System," published July 2014 in *JAMA Internal Medicine*, which found no evidence that the implementation of ICU telemedicine significantly reduced mortality rates or hospital length of stay, which could be indicators of clinical benefit. Therefore, we stated that we do not believe that the submitted evidence demonstrates a clinical benefit to patients. Therefore, we did not propose to add these services on a category 2 basis to the list of Medicare telehealth services for CY 2016 (80 FR 71061).

This year, requesters cited additional studies to support adding critical care services on a category 2 basis. Eight of the studies dealt with telestroke and one with teleneurology. Telestroke is an approach that allows a neurologist to provide remote treatment to vascular stroke victims. Teleneurology offers consultations for neurological problems from a remote location. It may be initiated by a physician or a patient, for conditions such as headaches, dementia, strokes, multiple sclerosis and epilepsy.

However, according to the literature, the management of stroke via telehealth requires more than a single practitioner and is distinct from the work described by the E/M codes. One additional study cited involved pediatric patients, while another noted that the Department of Defense has used telehealth to provide critical care services to hospitals in Guam for many years. Another reference study indicated that consulting intensivists thought that telemedicine consultations were superior to telephone consultations. In all of these cases, we believe the evidence demonstrates that interaction between these patients and distant site practitioners can have clinical benefit. However, we do not agree that the kinds of services described in the study are those that are included in the critical care E/M codes. We note that CPT guidance makes clear that a variety of other services are bundled into the payment rates for critical care, including gastric intubations and vascular access procedures among others We do not believe these kinds of services are furnished via telehealth. Public comments, included cited studies, can be viewed at *https://www.regulations.gov/#!documentDetail;D=CMS-2015-0081-0002*. Therefore, we are not proposing to add these services to the list of Medicare telehealth services for CY 2017.

However, we are persuaded by the requests that we recognize the potential benefit of critical care consultation services that are furnished remotely. We note that there are currently codes on the telehealth list that could be reported when consultation services are furnished to critically ill patients. But in consideration of these public requests, we recognize that there may be greater resource costs involved in furnishing these services relative to the existing telehealth consultation codes. We also agree with the requesters that there may be potential benefits of remote care by specialists for these patients. For these reasons, we think it would be advisable to create a coding distinction between telehealth consultations for critically ill patients relative to telehealth consultations for other hospital patients. Such a coding distinction would allow us to recognize the additional resource costs in terms of time and intensity involved in furnishing such services under the conditions where remote, intensive consultation is required to provide access to appropriate care for the critically ill patient. We recognize that the current set of codes may not adequately describe such services because current E/M coding presumes that the services are occurring in-person, in which case the expert care would be furnished in a manner described by the current codes for critical care.

Therefore, we are proposing to make payment through new codes, initial and subsequent, used to describe critical care consultations furnished via telehealth. This coding would provide a mechanism to report an intensive telehealth consultation service, initial or subsequent, for the critically ill patient under the circumstance when a qualified health care professional has in-person responsibility for the patient but the patient benefits from additional services from a distant-site consultant specially trained in providing critical care services. We propose limiting these services to once per day per patient. Like the other telehealth consultations, these services would be valued relative to existing E/M services (see Section II.L.2.b for proposed code valuations).

More details on the new coding (GTTT1 and GTTT2) and proposed valuation for these services are discussed in section II.L. of this proposed rule and the proposed RVUs for this service are included in Addendum B of this proposed rule. Like the other telehealth consultation codes, we are proposing that these services would be added to the telehealth list and would be subject to the geographic and other statutory restrictions that apply to telehealth services.

We request comment on this proposal, specifically as to whether the use of new coding would create a helpful distinction between telehealth consultations for critically ill patients relative to telehealth consultations for other hospital patients. We are also specifically interested in comments on how these services would be distinguished from existing critical care services and examples of different scenarios when each code would be appropriate. Such comments will help us to refine provider communication materials.

d. Psychological Testing: CPT Codes—

- 96101 (psychological testing (includes psychodiagnostic assessment of emotionality, intellectual abilities, personality and psychopathology, *e.g.,* MMPI, Rorschach, WAIS), per hour of the psychologist's or physician's time, both face-to-face time administering tests to the patient and time interpreting these test results and preparing the report);
- 96102 psychological testing (includes psychodiagnostic assessment of emotionality, intellectual abilities, personality and psychopathology, *e.g.,* MMPI and WAIS), with qualified health care professional interpretation and report, administered by technician, per hour of technician time, face-to-face);
- 96118 Neuropsychological testing (*e.g.,* Halstead-Reitan neuropsychological battery, Wechsler memory scales and Wisconsin card sorting test), per hour of the psychologist's or physician's time, both face-to-face time administering tests to the patient and time interpreting these test results and preparing the report); and,
- 96119 Neuropsychological testing (*e.g.,* Halstead-Reitan neuropsychological battery, Wechsler memory scales and Wisconsin card sorting test), with qualified health care professional interpretation and report, administered by technician, per hour of technician time, face-to-face).

Requesters indicated that there is nothing in the Minnesota Multiphasic Personality Inventory (MMPI), the Rorschach inkblot test, the Wechsler Adult Intelligence Scale (WAIS), the Halstead-Reitan Neuropsychological Battery and Allied Procedures, or the Wisconsin Card Sorting Test (WCST), that cannot be done via telehealth nor is different than neurological tests done for Parkinson's disease, seizure medication side effects, gait assessment, nor any of the many neurological examinations done via telehealth with the approved outpatient office visit and inpatient visit CPT codes currently on the telehealth list. As an example, requesters indicated that the MPPI is administered by a computer, which generates a report that is interpreted by the clinical psychologist, and that the test requires no interaction between the clinician and the patient.

We previously considered the request to add these codes to the Medicare telehealth list in the CY 2015 final rule (79 FR 67600). We decided not to add these codes, indicating that these services are not similar to other services on the telehealth list because they require close observation of how a patient responds. We noted that the requesters did not submit evidence supporting the clinical benefit of furnishing these services via telehealth so that we could evaluate them on a category 2 basis. While we acknowledge that requesters believe that some of these tests require minimal, if any, interaction between the clinician and patient, we disagree. We continue to believe that successful completion of the tests listed as examples in these codes require the clinical psychologist to closely observe the patient's response, which cannot be performed via telehealth. Some patient responses, for example, sweating and fine tremors, may be missed when the patient and examiner are not in the same room. Therefore, we are not proposing to add these services to the list of Medicare telehealth services for CY 2017.

e. Physical and Occupational Therapy and Speech-Language Pathology Services: CPT Codes—

- 92507 (treatment of speech, language, voice, communication, and auditory processing disorder; individual); and, 92508 (treatment of speech, language, voice, communication, and auditory processing disorder; group, 2 or more individuals); 92521 (evaluation of speech fluency (*e.g.*, stuttering, cluttering)); 92522 (evaluation of speech sound production (*e.g.*, articulation, phonological process, apraxia, dysarthria)); 92523 (evaluation of speech sound production (*e.g.*, articulation, phonological process, apraxia, dysarthria); with evaluation of language comprehension and expression (*e.g.*, receptive and expressive language)); 92524 (behavioral and qualitative analysis of voice and resonance); (evaluation of oral and pharyngeal swallowing function); 92526 (treatment of swallowing dysfunction or oral function for feeding); 92610 (evaluation of oral and pharyngeal swallowing function); CPT codes 97001 (physical therapy evaluation); 97002 (physical therapy re-evaluation); 97003 (occupational therapy evaluation); 97004 (occupational therapy re-evaluation); 97110 (therapeutic procedure, 1 or more areas, each 15 minutes; therapeutic exercises to develop strength and endurance, range of motion and flexibility); 97112 (therapeutic procedure, 1 or more areas, each 15 minutes; neuromuscular reeducation of movement, balance, coordination, kinesthetic sense, posture, or proprioception for sitting or standing activities); 97116 (therapeutic procedure, 1 or more areas, each 15 minutes; gait training (includes stair climbing)); 97532 (development of cognitive skills to improve attention, memory, problem solving (includes compensatory training), direct (one-on-one) patient contact, each 15 minutes); 97533 (sensory integrative techniques to enhance sensory processing and promote adaptive responses to environmental demands, direct (one-on-one) patient contact, each 15 minutes); 97535 (self-care/home management training (*e.g.*, activities of daily living (adl) and compensatory training, meal preparation, safety procedures, and instructions in use of assistive technology devices/adaptive equipment) direct one-on-one contact, each 15 minutes); 97537 (community/work reintegration training (*e.g.*, shopping, transportation, money management, avocational activities or work environment/modification analysis, work task analysis, use of assistive technology device/adaptive equipment), direct one-on-one contact, each 15 minutes); 97542 (wheelchair management (*e.g.*, assessment, fitting, training), each 15 minutes); 97750 (physical performance test or measurement (*e.g.*, musculoskeletal, functional capacity), with written report, each 15 minutes); 97755 (assistive technology assessment (*e.g.*, to restore, augment or compensate for existing function, optimize functional tasks and maximize environmental accessibility), direct one-on-one contact, with written report, each 15 minutes); 97760 Orthotic(s) management and training (including assessment and fitting when not otherwise reported), upper extremity(s), lower extremity(s) and/or trunk, each 15 minutes); 97761 (prosthetic training, upper and lower extremity(s), each 15 minutes); and 97762 (checkout for orthotic/prosthetic use, established patient, each 15 minutes).

The statute defines who is an authorized practitioner of telehealth services. Physical therapists, occupational therapists and speech-language pathologists are not authorized practitioners of telehealth under section 1834(m)(4)(E) of the Act, as defined in section 1842(b)(18)(C) of the Act. Because the above services are predominantly furnished by physical therapists, occupational therapists and speech-language pathologists, we do not believe it would be appropriate to add them to the list of telehealth services at this time. One requester suggested that we can add telehealth practitioners without legislation, as evidenced by the addition of nutritional professionals. However, we do not believe we have such authority and note that nutritional professionals are included as practitioners in the definition at section 1834(b)(18)(C)(vi) of the Act, and thus, are within the statutory definition of telehealth practitioners. Therefore, we are not proposing to add these services to the list of Medicare telehealth services for CY 2017.

In summary, we propose to add the following codes to the list of Medicare telehealth services beginning in CY 2017 on a category 1 basis:

- ESRD-related services 90967 through 90970. The required clinical examination of the catheter access site must be furnished face-to-face "hands on" (without the use of an interactive telecommunications system) by a physician, CNS, NP, or PA.
- Advance care planning (CPT codes 99497 and 99498).
- Telehealth Consultations for a Patient Requiring Critical Care Services (GTTT1 and GTTT2)

We remind all interested stakeholders that we are currently soliciting public requests to add services to the list of Medicare telehealth services. To be considered during PFS rulemaking for CY 2018, these requests must be submitted and received by December 31, 2016. Each request to add a service to the list of Medicare telehealth services must include any supporting documentation the requester wishes us to consider as we review the request. For more information on submitting a request for an addition to the list of Medicare telehealth services, including where to mail these requests, we refer readers to the CMS Web site at *https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/index.html.*

4. Place of Service (POS) Code for Telehealth Services

CMS has received multiple requests from various stakeholders to establish a POS code to identify services furnished via telehealth. These requests have come from other payers, but may also be related to confusion concerning whether to use the POS where the distant site physician is located or the POS where the patient is located. The process for establishing POS codes, is managed by the POS Workgroup within CMS, is available for use by all payers, and is not contingent upon Medicare PFS rulemaking. However, if such a POS code were to be created, in order to make it valid for use in Medicare, we would have to determine the appropriate payment rules associated with the code. Therefore, we are proposing how a POS code for telehealth would be used under the PFS with the expectation that, if such a code is available, it would be used as early as January 1, 2017. We propose that the physicians or practitioners furnishing telehealth services would be required to report the telehealth POS code to indicate that the billed service is furnished as a telehealth service from a distant site.

Our proposed requirement for physicians and practitioners to use the telehealth POS code to report that telehealth services were furnished from a distant site would improve payment accuracy and consistency in telehealth claims submission. Currently, for services furnished via telehealth, we have instructed practitioners to report the POS code that would have been reported had the service been furnished in person. However, some practitioners use the POS where they are located when the service is furnished, while others use the POS corresponding to the patient's location.

Under the PFS, the POS code determines whether a service is paid using the facility or non-facility practice expense relative value units (PE RVUs). The facility rate is paid when a service is furnished in a location where Medicare is making a separate facility payment to an entity other than the physician or practitioner that is intended to reflect the facility costs associated with the service (clinical staff, supplies and equipment). We note that in accordance with section 1834(m)(2)(B) of the Act, the payment amount for the telehealth facility fee paid to the originating site is a national fee, paid without geographic or site of service adjustments that generally are made for payments to different kinds of Medicare providers and suppliers. In the case of telehealth services, we believe that facility costs (clinical staff, supplies, and equipment) associated with the provision of the service would generally be incurred by the originating site, where the patient is located, and not by the practitioner at the distant site. And, by statute, the Medicare pays a fee to the site that hosts the patient. This is analogous to the circumstances under which the facility PE RVUs are used to pay for services under the PFS. Therefore, we are proposing to use the facility PE RVUs to pay for telehealth services reported by physicians or practitioners with the telehealth POS code. We note that there are only three codes on the telehealth list with a difference greater than 1.0 PE RVUs between the facility PE RVUs and the non-facility PE RVUs. The remainder of the physician payments for telehealth services would be unchanged by this proposal. We do not anticipate that this proposal would result in a significant change in the total payment for the majority of services on the telehealth list. Moreover, many practitioners already use a facility POS when billing for telehealth services (those that report the POS of the originating site where the beneficiary is located). The proposed policy to use the telehealth POS code for telehealth services would not affect payment for telehealth services for these practitioners.

The POS code for telehealth would not apply to originating sites billing the facility fee. Originating sites are not furnishing a service via telehealth since the patient is physically present in the facility. Accordingly, the originating site would continue to use the POS code that applies to the type of facility where the patient is located.

We are also proposing a change to our regulation at § 414.22(b)(5)(i)(A) that addresses the PE RVUs used in different settings. These proposed revisions would improve clarity regarding our current and proposed policies. Specifically, we are proposing to amend this section to specify that the facility PE RVUs are paid for practitioner services furnished via telehealth under § 410.78. In addition, we are proposing a change to resolve any potential ambiguity and clarify that payment under the PFS is made at the facility rate (facility PE RVUs) when services are furnished in a hospital but for which the hospital is not being paid. Finally, to streamline the existing regulation, we are also proposing to delete § 414.32 of our regulation that refers to the calculating of payments for certain services prior to 2002.

This proposed change is aligned with regulatory changes being proposed in the "Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Procurement Organization Reporting and Communication; Transplant Outcome Measures and Documentation Requirements; Electronic Health Record (EHR) Incentive Programs; Payment to Certain Off-Campus Provider-Based Departments" proposed rule to implement section 603 of the Bipartisan Budget Act of 2015. In that proposed rule, we discuss payment rates for services furnished to patients in off-campus provider-based departments.

D. Potentially Misvalued Services Under the Physician Fee Schedule

1. Background

Section 1848(c)(2)(B) of the Act directs the Secretary to conduct a periodic review, not less often than every 5 years, of the RVUs established under the PFS. Section 1848(c)(2)(K) of the Act requires the Secretary to periodically identify potentially misvalued services using certain criteria and to review and make appropriate adjustments to the relative values for those services. Section 1848(c)(2)(L) to the Act also requires the Secretary to develop a process to validate the RVUs of certain potentially misvalued codes under the PFS, using the same criteria used to identify potentially misvalued codes, and to make appropriate adjustments.

As discussed in section II.B. of this proposed rule, each year we develop appropriate adjustments to the RVUs taking into account recommendations provided by the American Medical Association/Specialty Society Relative Value Scale Update Committee (RUC), the Medicare Payment Advisory Commission (MedPAC), and others. For many years, the RUC has provided us with recommendations on the appropriate relative values for new, revised, and potentially misvalued PFS services. We review these recommendations on a code-by-code basis and consider these recommendations in conjunction with analyses of other data, such as claims data, to inform the decision-making process as authorized by the law. We may also consider analyses of work time, work RVUs, or direct PE inputs using other data sources, such as Department of Veteran Affairs (VA), National Surgical Quality Improvement Program (NSQIP), the Society for Thoracic Surgeons (STS), and the Physician Quality Reporting System (PQRS) databases. In addition to considering the most recently available data, we also assess the results of physician surveys and specialty recommendations submitted to us by the RUC for our review. We also consider information provided by other stakeholders. We conduct a review to assess the appropriate RVUs in the context of contemporary medical practice. We note that section 1848(c)(2)(A)(ii) of the Act authorizes the use of extrapolation and other techniques to determine the RVUs for physicians' services for which specific data are not available and requires us to take into account the results of consultations with organizations representing physicians who provide the services. In accordance with section 1848(c) of the Act, we determine and make appropriate adjustments to the RVUs.

In its March 2006 Report to the Congress (*http://www.medpac.gov/documents/reports/Mar06_EntireReport.pdf?sfvrsn=0*), MedPAC discussed the importance of appropriately valuing physicians' services, noting that misvalued services can distort the market for physicians' services, as well as for other health care services that physicians order, such as hospital services. In that same report MedPAC postulated that physicians' services under the PFS can become misvalued over time. MedPAC stated, "When a new service is added to the physician fee schedule, it may be assigned a relatively high value because of the time, technical skill, and psychological stress that are often required to furnish that service. Over time, the work required for certain services would be expected to decline as physicians become more familiar with the service and more efficient in furnishing it." We believe services can also become overvalued when PE declines. This can happen when the costs of equipment and supplies fall, or when equipment is used more frequently than is estimated in the PE methodology, reducing its cost per use. Likewise, services can become undervalued when physician work increases or PE rises.

As MedPAC noted in its March 2009 Report to Congress (*http://www.medpac.gov/documents/reports/march-2009-report-to-congress-medicare-payment-policy.pdf?sfvrsn=0*), in the intervening years since MedPAC made the initial recommendations, CMS and the RUC have taken several steps to improve the review process. Also, section 1848(c)(2)(K)(ii) of the Act augments our efforts by directing the Secretary to specifically examine, as determined appropriate, potentially misvalued services in the following categories:

- Codes that have experienced the fastest growth.
- Codes that have experienced substantial changes in practice expenses.
- Codes that describe new technologies or services within an appropriate time period (such as 3 years) after the relative values are initially established for such codes.
- Codes which are multiple codes that are frequently billed in conjunction with furnishing a single service.
- Codes with low relative values, particularly those that are often billed multiple times for a single treatment.
- Codes that have not been subject to review since implementation of the fee schedule.
- Codes that account for the majority of spending under the physician fee schedule.
- Codes for services that have experienced a substantial change in the hospital length of stay or procedure time.
- Codes for which there may be a change in the typical site of service since the code was last valued.
- Codes for which there is a significant difference in payment for the same service between different sites of service.
- Codes for which there may be anomalies in relative values within a family of codes.
- Codes for services where there may be efficiencies when a service is furnished at the same time as other services.
- Codes with high intra-service work per unit of time.
- Codes with high practice expense relative value units.
- Codes with high cost supplies.
- Codes as determined appropriate by the Secretary.

Section 1848(c)(2)(K)(iii) of the Act also specifies that the Secretary may use existing processes to receive recommendations on the review and appropriate adjustment of potentially misvalued services. In addition, the Secretary may conduct surveys, other data collection activities, studies, or other analyses, as the Secretary determines to be appropriate, to facilitate the review and appropriate adjustment of potentially misvalued services. This section also authorizes the use of analytic contractors to identify and analyze potentially misvalued codes, conduct surveys or collect data, and make recommendations on the review and appropriate adjustment of potentially misvalued services. Additionally, this section provides that the Secretary may coordinate the review and adjustment of any RVU with the periodic review described in section 1848(c)(2)(B) of the Act. Section 1848(c)(2)(K)(iii)(V) of the Act specifies that the Secretary may make appropriate coding revisions (including using existing processes for consideration of coding changes) that may include consolidation of individual services into bundled codes for payment under the physician fee schedule.

2. Progress in Identifying and Reviewing Potentially Misvalued Codes

To fulfill our statutory mandate, we have identified and reviewed numerous potentially misvalued codes as specified in section 1848(c)(2)(K)(ii) of the Act, and we plan to continue our work examining potentially misvalued codes in these areas over the upcoming years. As part of our current process, we identify potentially misvalued codes for review, and request recommendations from the RUC and other public commenters on revised work RVUs and direct PE inputs for those codes. The RUC, through its own processes, also identifies potentially misvalued codes for review. Through our public nomination process for potentially misvalued codes established in the CY 2012 PFS final rule with comment period, other individuals and stakeholder groups submit nominations for review of potentially misvalued codes as well.

Since CY 2009, as a part of the annual potentially misvalued code review and Five-Year Review process, we have reviewed over 1,671 potentially misvalued codes to refine work RVUs and direct PE inputs. We have assigned appropriate work RVUs and direct PE inputs for these services as a result of these reviews. A more detailed discussion of the extensive prior reviews of potentially misvalued codes is included in the CY 2012 PFS final rule with comment period (76 FR 73052 through 73055). In the CY 2012 PFS final rule with comment period, we finalized our policy to consolidate the review of physician work and PE at the same time (76 FR 73055 through 73958), and established a process for the annual public nomination of potentially misvalued services.

In the CY 2013 PFS final rule with comment period, we built upon the work we began in CY 2009 to review potentially misvalued codes that have not been reviewed since the implementation of the PFS (so-called "Harvard-valued codes"). In CY 2009, we requested recommendations from the RUC to aid in our review of Harvard-valued codes that had not yet been reviewed, focusing first on high-volume, low intensity codes (73 FR 38589). In the fourth Five-Year Review (76 FR 32410), we requested recommendations from the RUC to aid in our review of Harvard-valued codes with annual utilization of greater than 30,000. In the CY 2013 PFS final rule with comment period, we identified specific Harvard-valued services with annual allowed charges that total at least $10,000,000 as potentially misvalued. In addition to the Harvard-valued codes, in the CY 2013 PFS final rule with comment period we finalized for review a list of potentially misvalued codes that have stand-alone PE (codes with physician work and no listed work time and codes with no physician work that have listed work time).

In the CY 2016 PFS final rule with comment period, we finalized for review a list of potentially misvalued services, which included eight codes in the neurostimulators analysis-programming family (CPT 95970–95982). We also finalized as potentially misvalued 103 codes identified through our screen of high expenditure services across specialties.

3. Validating RVUs of Potentially Misvalued Codes

Section 1848(c)(2)(L) of the Act requires the Secretary to establish a formal process to validate RVUs under the PFS. The Act specifies that the validation process may include validation of work elements (such as time, mental effort and professional judgment, technical skill and physical effort, and stress due to risk) involved with furnishing a service and may include validation of the pre-, post-, and intra-service components of work. The Secretary is directed, as part of the validation, to validate a sampling of the work RVUs of codes identified through any of the 16 categories of potentially misvalued codes specified in section 1848(c)(2)(K)(ii) of the Act. Furthermore, the Secretary may conduct the validation using methods similar to those used to review potentially misvalued codes, including conducting surveys, other data collection activities, studies, or other analyses as the Secretary determines to be appropriate to facilitate the validation of RVUs of services.

In the CY 2011 PFS proposed rule (75 FR 40068) and CY 2012 PFS proposed rule (76 FR 42790), we solicited public comments on possible approaches, methodologies, and data sources that we should consider for a validation process. A summary of the comments along with our responses are included in the CY 2011 PFS final rule with comment period (75 FR 73217) and the CY 2012 PFS final rule with comment period (73054 through 73055).

We contracted with two outside entities to develop validation models for RVUs.

Given the central role of time in establishing work RVUs and the concerns that have been raised about the current time values used in rate setting, we contracted with the Urban Institute to develop empirical time estimates based on data collected from several health systems with multispecialty group practices. The Urban Institute collected data by directly observing the delivery of services and through the use of electronic health records for services selected by the contractor in consultation with CMS and is using this data to produce objective time estimates. We expect the final Urban Institute report will be made available on the CMS Web site later this summer.

The second contract is with the RAND Corporation, which used available data to build a validation model to predict work RVUs and the individual components of work RVUs, time and intensity. The model design was informed by the statistical methodologies and approach used to develop the initial work RVUs and to identify potentially misvalued procedures under current CMS and RUC processes. RAND consulted with a technical expert panel on model design issues and the test results. The RAND report is available under downloads on the Web site for the CY 2015 PFS Final Rule with Comment Period at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices-Items/CMS–1612–FC.html.*

After posting RAND's report on the models and results on our Web site, we received comments indicating that the models did not adequately address global surgery services due to the lack of available data on included visits. Therefore, we modified the RAND contract to include the development of G-codes that could be used to collect data about post-surgical follow-up visits on Medicare claims to meet the requirements in section 1848(c)(8)(B) of the Act regarding collection of data on global services. Our proposals related to this data collection requirement are discussed in section II.D.6. Also, the data from this project would provide information that would allow the time for these services to be included in the model for validating RVUs.

4. CY 2017 Identification and Review of Potentially Misvalued Services

a. 0-day Global Services That Are Typically Billed With an Evaluation and Management (E/M) Service With Modifier 25

Because routine E/M is included in the valuation of codes with 0-, 10-, and 90-day global periods, Medicare only makes separate payment for E/M services that are provided in excess of those considered included in the global procedure. In such cases, the physician would report the additional E/M service with Modifier 25, which is defined as a significant, separately identifiable E/M service performed by the same physician on the day of a procedure above and beyond other services provided or beyond the usual preservice and postservice care associated with the procedure that was performed. Modifier 25 allows physicians to be paid for E/M services that would otherwise be denied as bundled.

In reviewing misvalued codes, both CMS and the RUC have often considered how frequently particular codes are reported with E/M codes to account for potential overlap in resources. Some stakeholders have expressed concern with this policy especially with regard to the valuation of 0-day global services that are typically billed with a separate E/M service with the use of Modifier 25. For example, when we established our valuation of the osteopathic manipulation services, described by CPT codes 98925–98929, we did so with the understanding that these codes are usually reported with E/M codes.

Medicare claims data for CY 2015 show that 19 percent of the codes that describe 0-day global services were billed over 50 percent of the time with an E/M with Modifier 25. Since routine E/M is included in the valuation of 0-day global services, we believe that the routine billing of separate E/M services may indicate a possible problem with the valuation of the bundle, which is intended to include all the routine care associated with the service.

We believe that reviewing the procedure codes typically billed with an E/M with Modifier 25 as potentially misvalued may be one avenue to improve valuation of these services. To develop the CY 2017 proposed list of potentially misvalued services in this category, we identified 0-day global codes billed with an E/M 50 percent of the time or more, on the same day of service, with the same physician and same beneficiary. To prioritize review of these potentially misvalued services, we are identifying the codes that have not been reviewed in the last 5 years, and with greater than 20,000 allowed services. Table 7 lists the 83 codes that meet these review criteria and we are proposing these as potentially misvalued for CY 2017. We request public input on additional ways to address appropriate valuations for all services that are typically billed with an E/M with Modifier 25.

Table 7—0-Day Global Services That Are Typically Billed With an Evaluation and Management (E/M) Service With Modifier 25

HCPCS	Long descriptor
11000	Removal of inflamed or infected skin, up to 10% of body surface.
11100	Biopsy of single growth of skin or tissue.
11300	Shaving of 0.5 centimeters or less skin growth of the trunk, arms, or legs.
11301	Shaving of 0.6 centimeters to 1.0 centimeters skin growth of the trunk, arms, or legs.
11302	Shaving of 1.1 to 2.0 centimeters skin growth of the trunk, arms, or legs.
11305	Shaving of 0.5 centimeters or less skin growth of scalp, neck, hands, feet, or genitals.
11306	Shaving of 0.6 centimeters to 1.0 centimeters skin growth of scalp, neck, hands, feet, or genitals.
11307	Shaving of 1.1 to 2.0 centimeters skin growth of scalp, neck, hands, feet, or genitals.
11310	Shaving of 0.5 centimeters or less skin growth of face, ears, eyelids, nose, lips, or mouth.
11311	Shaving of 0.6 centimeters to 1.0 centimeters skin growth of face, ears, eyelids, nose, lips, or mouth.
11312	Shaving of 1.1 to 2.0 centimeters skin growth of face, ears, eyelids, nose, lips, or mouth.
11740	Removal of blood accumulation between nail and nail bed.
11755	Biopsy of finger or toe nail.
11900	Injection of up to 7 skin growths.
11901	Injection of more than 7 skin growths.
12001	Repair of wound (2.5 centimeters or less) of the scalp, neck, underarms, trunk, arms or legs.
12002	Repair of wound (2.6 to 7.5 centimeters) of the scalp, neck, underarms, genitals, trunk, arms or legs.
12004	Repair of wound (7.6 to 12.5 centimeters) of the scalp, neck, underarms, genitals, trunk, arms or legs.
12011	Repair of wound (2.5 centimeters or less) of the face, ears, eyelids, nose, lips, or mucous membranes.
12013	Repair of wound (2.6 to 5.0 centimeters) of the face, ears, eyelids, nose, lips, or mucous membranes.
17250	Application of chemical agent to excessive wound tissue.
20526	Injection of carpal tunnel.
20550	Injections of tendon sheath, ligament, or muscle membrane.
20551	Injections of tendon attachment to bone.
20552	Injections of trigger points in 1 or 2 muscles.
20553	Injections of trigger points in 3 or more muscles.
20600	Aspiration or injection of small joint or joint capsule.
20604	Arthrocentesis, aspiration or injection, small joint or bursa (e.g., fingers, toes); with ultrasound guidance, with permanent recording and reporting.
20605	Aspiration or injection of medium joint or joint capsule.
20606	Arthrocentesis, aspiration or injection, intermediate joint or bursa (e.g., temporomandibular, acromioclavicular, wrist, elbow or ankle, olecranon bursa); with ultrasound guidance, with permanent recording and reporting.
20610	Aspiration or injection of large joint or joint capsule.
20611	Arthrocentesis, aspiration or injection, major joint or bursa (e.g., shoulder, hip, knee, subacromial bursa); with ultrasound guidance, with permanent recording and reporting.
20612	Aspiration or injection of cysts.
29105	Application of long arm splint (shoulder to hand).
29125	Application of non-moveable, short arm splint (forearm to hand).
29515	Application of short leg splint (calf to foot).
29540	Strapping of ankle or foot.
29550	Strapping of toes.
30901	Simple control of nose bleed.
30903	Complex control of nose bleed.
31231	Diagnostic examination of nasal passages using an endoscope.
31238	Control of nasal bleeding using an endoscope.
31500	Emergent insertion of breathing tube into windpipe cartilage using an endoscope.
31575	Diagnostic examination of voice box using flexible endoscope.
31579	Examination to assess movement of vocal cord flaps using an endoscope.
31645	Aspiration of lung secretions from lung airways using an endoscope.
32551	Removal of fluid from between lung and chest cavity, open procedure.
32554	Removal of fluid from chest cavity.
40490	Biopsy of lip.
43760	Change of stomach feeding, accessed through the skin.
45300	Diagnostic examination of rectum and large bowel using an endoscope.
46600	Diagnostic examination of the anus using an endoscope.
51701	Insertion of temporary bladder catheter.
51702	Insertion of indwelling bladder catheter.
51703	Insertion of indwelling bladder catheter.
56605	Biopsy of external female genitals.
57150	Irrigation of vagina or application of drug to treat infection.
57160	Fitting and insertion of vaginal support device.
58100	Biopsy of uterine lining.
64405	Injection of anesthetic agent, greater occipital nerve.
64418	Injection of anesthetic agent, collar bone nerve.
64455	Injections of anesthetic or steroid drug into nerve of foot.
65205	Removal of foreign body in external eye, conjunctiva.
65210	Removal of foreign body in external eye, conjunctiva or sclera.
65222	Removal of foreign body, external eye, cornea with slit lamp examination.
67515	Injection of medication or substance into membrane covering eyeball.
67810	Biopsy of eyelid.
67820	Removal of eyelashes by forceps.

TABLE 7—0-DAY GLOBAL SERVICES THAT ARE TYPICALLY BILLED WITH AN EVALUATION AND MANAGEMENT (E/M) SERVICE WITH MODIFIER 25—Continued

HCPCS	Long descriptor
68200	Injection into conjunctiva.
69100	Biopsy of ear.
69200	Removal of foreign body from ear canal.
69210	Removal of impact ear wax, one ear.
69220	Removal of skin debris and drainage of mastoid cavity.
92511	Examination of the nose and throat using an endoscope.
92941	Insertion of stent, removal of plaque or balloon dilation of coronary vessel during heart attack, accessed through the skin.
92950	Attempt to restart heart and lungs.
98925	Osteopathic manipulative treatment to 1–2 body regions.
98926	Osteopathic manipulative treatment to 3–4 body regions.
98927	Osteopathic manipulative treatment to 5–6 body regions.
98928	Osteopathic manipulative treatment to 7–8 body regions.
98929	Osteopathic manipulative treatment to 9–10 body regions.
G0168	Wound closure utilizing tissue adhesive(s) only.
G0268	Removal of impacted cerumen (one or both ears) by physician on same date of service as audiologic function testing.

b. End-Stage Renal Disease Home Dialysis Services (CPT Codes 90963 Through 90970)

In the CY 2004 PFS final rule with comment period (68 FR 63216), we established new Level II HCPCS G-codes for end-stage renal disease (ESRD) services and established payment for those codes through monthly capitation payment (MCP) rates. For ESRD center-based patients, payment for the G-codes varied based on the age of the beneficiary and the number of face-to-face visits furnished each month (for example, 1 visit, 2–3 visits and 4 or more visits). We believed that many physicians would provide 4 or more visits to center-based ESRD patients and a small proportion will provide 2–3 visits or only one visit per month. Under the MCP methodology, to receive the highest payment, a physician would have to provide at least four ESRD-related visits per month. However, payment for home dialysis MCP services only varied by the age of beneficiary. Although we did not initially specify a frequency of required visits for home dialysis MCP services, we stated that we expect physicians to provide clinically appropriate care to manage the home dialysis patient.

The CPT Editorial Panel created new CPT codes to replace the G-codes for monthly ESRD-related services, and we accepted the new codes for use under the PFS in CY 2009. The CPT codes created were 90963–90966 for monthly ESRD-related services for home dialysis patient and CPT codes 90967–90970 for dialysis with less than a full month of services.

In a GAO report titled "END-STAGE RENAL DISEASE Medicare Payment Refinements Could Promote Increased Use of Home Dialysis" dated October 2015, *http://www.gao.gov/products/GAO-16-125,* the GAO stated that experts and stakeholders they interviewed indicated that home dialysis could be clinically appropriate for at least half of patients. Also, at a meeting in 2013, the chief medical officers of 14 dialysis facility chains jointly estimated that a realistic target for home dialysis would be 25 percent of dialysis patients. The GAO noted that CMS data showed that about 10 percent of adult Medicare dialysis patients use home dialysis as of March 2015.

In the report, the GAO noted that CMS intended for the existing payment structure to create an incentive for physicians to prescribe home dialysis, because the monthly payment rate for managing the dialysis care of home patients, which requires a single in-person visit, was approximately equal to the rate for managing and providing two to three visits to ESRD center-based patients. However, GAO found that, in 2013, the rate of $237 for managing home patients was lower than the average payment of $266 and maximum payment of $282 for managing ESRD center-based patients. The GAO stated that this difference in payment rates may discourage physicians from prescribing home dialysis.

Physician associations and other physicians GAO interviewed stated that the visits with home patients are often longer and more comprehensive than in-center visits; this is in part because physicians may conduct visits with individual home patients in a private setting, but they may be able to more easily visit multiple in-center patients on a single day as they receive dialysis. The physician associations GAO interviewed also said that they may spend a similar amount of time outside of visits to manage the care of home patients and that they are required to provide at least one visit per month to perform a complete assessment of the patient.

It is important to note that, as stated in the CY 2011 PFS final rule with comment period (75 FR 73296), we believe that furnishing monthly face-to-face visits is an important component of high quality medical care for ESRD patients being dialyzed at home and generally would be consistent with the current standards of medical practice. However, we also acknowledged that extenuating circumstances may arise that make it difficult for the MCP physician (or NPP) to furnish a visit to a home dialysis patient every month. Therefore, we allow Medicare contractors the discretion to waive the requirement for a monthly face-to-face visit for the home dialysis MCP service on a case-by-case basis, for example, when the MCP physician's (or NPP's) notes indicate that the MCP physician (or NPP) actively and adequately managed the care of the home dialysis patient throughout the month.

The GAO recommended, and we agreed, that CMS examine Medicare policies for monthly payments to physicians to manage the care of dialysis patients and revise them if necessary to ensure that these policies are consistent with our goal of encouraging the use of home dialysis among patients for whom it is appropriate. Therefore, we are proposing to identify CPT codes 90963 through 90970 as potentially misvalued codes based on the volume of claims submitted for these services relative to those submitted for facility ESRD services.

c. Direct PE Input Discrepancies

i. Appropriate Direct PE Inputs Involved in Procedures Involving Endoscopes

Stakeholders have raised concerns about potential inconsistencies with the inputs and the prices related to endoscopic procedures in the direct PE database. Upon review, we noted that there are 45 different pieces of endoscope related-equipment and 25 different pieces of endoscope related-supplies that are currently associated with these services. Relative to other kinds of equipment items in the direct PE input, these items are much more varied and used for many fewer services. Given the frequency with which individual codes can be reviewed and the importance of standardizing inputs for purposes of maintaining relativity across PFS services, we believe that this unusual degree of variation is likely to result in code misvaluation. To facilitate efficient review of this particular kind of misvaluation, and because we believe that stakeholders will prefer the opportunity to contribute to such standardization, we request that stakeholders like the RUC review and make recommendations on the appropriate endoscopic equipment and supplies typically provided in all endoscopic procedures for each anatomical body region, along with their appropriate prices.

ii. Appropriate Direct PE Inputs in the Facility Post-Service Period When Post-Operative Visits Are Excluded

We identified a potential inconsistency in instances where there are direct PE inputs included in the facility postservice period even though post-operative visit is not included in a service. We identified 13 codes that are affected by this issue and we are unclear if the discrepancy is caused by inaccurate direct PE inputs or inaccurate post-operative data in the work time file. We request that stakeholders including the RUC review these discrepancies and provide their recommendations on the appropriate direct PE inputs for the codes listed in Table 8.

TABLE 8—CODES THAT HAVE DIRECT PE INPUTS IN THE FACILITY POSTSERVICE PERIOD WHEN POST-OPERATIVE VISITS ARE EXCLUDED

CPT Code	Long descriptor
21077	Impression and preparation of eye socket prosthesis.
21079	Impression and custom preparation of temporary oral prosthesis.
21080	Impression and custom preparation of permanent oral prosthesis.
21081	Impression and custom preparation of lower jaw bone prosthesis.
21082	Impression and custom preparation of prosthesis for roof of mouth enlargement.
21083	Impression and custom preparation of roof of mouth prosthesis.
21084	Impression and custom preparation of speech aid prosthesis.
28636	Insertion of hardware to foot bone dislocation with manipulation, accessed through the skin.
28666	Insertion of hardware to toe joint dislocation with manipulation, accessed through the skin.
43652	Incision of vagus nerves of stomach using an endoscope.
46900	Chemical destruction of anal growths.
47570	Connection of gall bladder to bowel using an endoscope.
66986	Exchange of lens prosthesis.

d. Insertion and Removal of Drug Delivery Implants—CPT Codes 11981 and 11983

Stakeholders have urged CMS to create new coding describing the insertion and removal of drug delivery implants for buprenorphine hydrochloride, formulated as a 4 rod, 80 mg, long acting subdermal drug implant for the treatment of opioid addiction. These stakeholders have suggested that current coding that describes insertion and removal of drug delivery implants is too broad and that new coding is needed to account for specific additional resource costs associated with particular treatment. We are identifying existing CPT codes 11981 (Insertion, non-biodegradable drug delivery implant), 11982 (Removal, non-biodegradable drug delivery implant), and 11983 (Removal with reinsertion, non-biodegradable drug delivery implant) as potentially misvalued codes and are seeking comment and information regarding whether the current resource inputs in work and practice expense for these codes appropriately account for variations in the service relative to which devices and related drugs are inserted and removed.

5. Valuing Services That Include Moderate Sedation as an Inherent Part of Furnishing the Procedure

The CPT manual identifies more than 400 diagnostic and therapeutic procedures (listed in Appendix G) for which the CPT Editorial Committee has determined that moderate sedation is an inherent part of furnishing the procedure. In developing RVUs for these services, we include the resource costs associated with moderate sedation in the valuation since the CPT codes include moderate sedation as an inherent part of the procedure. Therefore, only the procedure code is currently reported when furnishing the service. Endoscopic procedures constitute a significant portion of the services identified in Appendix G. In the CY 2015 PFS proposed rule (79 FR 40349), we noted that it appeared that practice patterns for endoscopic procedures were changing, with anesthesia increasingly being separately reported for these procedures, meaning that the resource costs associated with sedation were no longer incurred by the practitioner reporting the Appendix G procedure. We indicated that, in order to reflect apparent changes in medical practice, we were considering establishing a uniform approach to the appropriate valuation of all Appendix G services for which moderate sedation is no longer inherent, rather than addressing the issue at the procedure level as individual codes are revalued. We solicited public comment on approaches to the appropriate valuation of these services.

In the CY 2016 PFS proposed rule (80 FR 41707), we again solicited public comment and recommendations on approaches to address the appropriate valuation of moderate sedation related to Appendix G services. In response to our comment solicitation, the CPT Editorial Panel created CPT codes for separately reporting moderate sedation services in association with the elimination of Appendix G from the CPT Manual for CY 2017. This coding change would provide for payment for moderate sedation services only in cases where it is furnished. In addition to providing recommended values for the new codes used to separately report moderate sedation, the RUC has also provided a methodology for revaluing all services previously identified in Appendix G, without moderate sedation, in order to make appropriate corresponding adjustments for the procedural services. The RUC recommended this methodology to address moderate sedation valuation generally instead of recommending that it be addressed as individual codes are reviewed. The RUC's recommended methodology would remove work RVUs for moderate sedation from Appendix G codes based on a code-level assessment of whether the procedures are typically performed on straightforward patients or more difficult patients. Based on its recommended methodology, the RUC is recommending removal of fewer RVUs from each of the procedural services than it recommends for valuing the moderate sedation services. If we were to use the RUC-recommended values for both the moderate sedation codes and the Appendix G procedural codes without refinement, overall payments for these procedures, when moderate sedation is furnished, would increase relative to the current payment.

We direct readers to section II.L. of this proposed rule, which includes more details regarding our proposed valuation of the new moderate sedation codes and our proposed uniform methodology for revaluation of the procedural codes previously identified in Appendix G. We believe that the RVUs assigned under the PFS should reflect the overall resource costs of PFS services, regardless of how many codes are used to report the services. Therefore, our proposed methodology for valuation of Appendix G procedural services would maintain current resource assumptions for the procedures when furnished with moderate sedation and redistribute the RVUs associated with moderate sedation (previously included in Appendix G procedural codes) to other PFS services. We believe that our proposed uniform methodology for revaluation of Appendix G services without moderate sedation is consistent with our general principle that the overall resource costs for the procedures do not change based solely on changes in coding.

We also note that stakeholders presented information to CMS regarding specialty group survey data for physician work. The stakeholders shared survey results for physician work involved in furnishing moderate sedation that demonstrated a significant bimodal distribution between procedural services furnished by gastroenterologists (GI) and procedural services furnished by other specialties. Since we believe that gastroenterologists furnish the highest volume of services previously identified in Appendix G, and services primarily furnished by gastroenterologists prompted the concerns that led to our identification of changes in medical practice and potentially duplicative payment for these codes, we have addressed the variations between the GI and other specialties in our review of the new moderate sedation CPT codes and their recommended values. We again direct readers to section II.L. of this proposed rule where we discuss our proposal to augment the new CPT codes for moderate sedation with an endoscopy-specific moderate sedation code, as well as proposed valuations reflecting the differences in the physician survey data between GI and other specialties.

6. Collecting Data on Resources Used in Furnishing Global Services

a. Background

(1) Current Payment Policy for Global Packages

Under the PFS, certain services, such as surgery, are valued and paid for as part of global packages that include the procedure and the services typically furnished in the periods immediately before and after the procedure. For each of these global packages, we establish a single PFS payment that includes payment for particular services that we assume to be typically furnished during the established global period. There are three primary categories of global packages that are labeled based on the number of post-operative days included in the global period: 0-day; 10-day; and 90-day. The 0-day global packages include the surgical procedure and the pre-operative and post-operative services furnished by the physician on the day of the service. The 10-day global packages include these services and, in addition, visits related to the procedure during the 10 days following the day of the procedure. The 90-day global packages include the same services as the 0-day global codes plus the pre-operative services furnished one day prior to the procedure and post-operative services during the 90 days immediately following the day of the procedure. Section 40.1 of Chapter 12 of the Claims Processing Manual (Pub. 100–04) defines the global surgical package to include the following services related to the surgery when furnished during the global period by the same physician or another practitioner in the same group practice:

- *Pre-operative Visits:* Pre-operative visits after the decision is made to operate beginning with the day before the day of surgery for major procedures and the day of surgery for minor procedures;
- *Intra-operative Services:* Intra-operative services that are normally a usual and necessary part of a surgical procedure;
- *Complications Following Surgery:* All additional medical or surgical services required of the surgeon during the post-operative period of the surgery because of complications that do not require additional trips to the operating room;
- *Post-operative Visits:* Follow-up visits during the post-operative period of the surgery that are related to recovery from the surgery;
- *Post-surgical Pain Management:* By the surgeon;
- *Supplies:* Except for those identified as exclusions; and
- *Miscellaneous Services:* Items such as dressing changes; local incisional care; removal of operative pack; removal of cutaneous sutures and staples, lines, wires, tubes, drains, casts, and splints; insertion, irrigation and removal of urinary catheters, routine peripheral intravenous lines, nasogastric and rectal tubes; and changes and removal of tracheostomy tubes.

In the CY 2015 PFS proposed and final rules we extensively discussed the problems with accurate valuation of 10- and 90-day global packages. Our concerns included the fact that we do not use actual data on services furnished in order to update the rates, questions regarding the accuracy of our current assumptions about typical services, whether we will be able to adjust values on a regular basis to reflect changes in the practice of medicine and health care delivery, and how our global payment policies affect what services are actually furnished (79 FR 67582 through 67585). In finalizing a policy to transform all 10-day and 90-day global codes to 0-day global codes in CY 2017 and CY 2018, respectively, to improve the accuracy of valuation and payment for the various components of global packages, including pre- and post-operative visits and the procedure itself, we stated that we were adopting this policy because we believe it is critical that PFS payment rates be based upon RVUs that reflect the resource costs of furnishing the services. We also stated our belief that transforming all 10- and 90-day global codes to 0-day global packages would:

- Increase the accuracy of PFS payment by setting payment rates for individual services that more closely reflect the typical resources used in furnishing the procedures;
- Avoid potentially duplicative or unwarranted payments when a beneficiary receives post-operative care from a different practitioner during the global period;
- Eliminate disparities between the payment for E/M services in global periods and those furnished individually;
- Maintain the same-day packaging of pre- and post-operative physicians' services in the 0-day global packages; and
- Facilitate the availability of more accurate data for new payment models and quality research.

(2) Data Collection and Revaluation of Global Packages Required by MACRA

Section 523(a) of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10, enacted April 16, 2015) prohibits the Secretary from implementing the policy, described above, that would have transformed all 10-day and 90-day global surgery packages to 0-day global packages.

Section 1848(c)(8)(B) of the Act, which was also added by section 523(a) of the MACRA, requires us to collect data to value surgical services. Section 1848(c)(8)(B)(i) of the Act requires us to develop, through rulemaking, a process to gather information needed to value surgical services from a representative sample of physicians, and requires that the data collection begin no later than January 1, 2017. The collected information must include the number and level of medical visits furnished during the global period and other items and services related to the surgery and furnished during the global period, as appropriate. This information must be reported on claims at the end of the global period or in another manner specified by the Secretary. Section 1848(c)(8)(B)(ii) of the Act requires that, every 4 years, we reassess the value of this collected information; and allows us to discontinue the collection of this information if the Secretary determines that we have adequate information from other sources to accurately value global surgical services. Section 1848(c)(8)(B)(iii) of the Act specifies that the Inspector General shall audit a sample of the collected information to verify its accuracy. Section 1848(c)(9) of the Act (added by section 523(b) of the MACRA) authorizes the Secretary, through rulemaking, to delay up to 5 percent of the PFS payment for services for which a physician is required to report information under section 1848(c)(8)(B)(i) of the Act until the required information is reported.

Section 1848(c)(8)(C) of the Act, which was also added by section 523(a) of the MACRA, requires that, beginning in CY 2019, we must use the information collected as appropriate, along with other available data, to improve the accuracy of valuation of surgical services under the PFS.

(3) Public Input

As noted above, section 1848(c)(8)(C) of the Act mandates that we use the collected data to improve the accuracy of valuation of surgery services beginning in 2019. We described in the CY 2015 PFS final rule (79 FR 67582 through 67591) the limitations and difficulties involved in the appropriate valuation of the global packages, especially when the resources and the related values assigned to the component services are not defined. To gain input from stakeholders on implementation of this data collection, we sought comment on various aspects of this task in the CY 2016 proposed rule (80 FR 41707 through 41708). We solicited comments from the public regarding the kinds of auditable, objective data (including the number and type of visits and other services furnished during the post-operative period by the practitioner furnishing the procedure) needed to increase the accuracy of the values for surgical services. We also solicited comment on the most efficient means of acquiring these data as accurately and efficiently as possible. For example, we sought information on the extent to which individual practitioners or practices may currently maintain their own data on services, including those furnished during the post-operative period, and how we might collect and objectively evaluate those data for use in increasing the accuracy of the values beginning in CY 2019.

We received many comments regarding potential methods of valuing the individual components of the global surgical package. A large number of comments expressed strong support for our proposal to hold an open door forum or town hall meetings with the public. Toward this end, we held a national listening session on January 20, 2016. Prior to the listening session, the topics for which guidance was being sought were sent electronically to those who registered for the session and made available on our Web site. The topics were:

- Mechanisms for capturing the types of services typically furnished during the global period.
- Determining the representative sample for the claims-based data collection.
- Determining whether we should collect data on all surgical services or, if not, which services should be sampled.
- Potential for designing data collection elements to interface with existing infrastructure used to track follow-up visits within the global period.
- Consideration of use of 5 percent withhold until required information is furnished.

The 658 participants in the national listening session provided valuable information on this task. A written transcript and an audio recording of this session are available at *https://www.cms.gov/Outreach-and-Education/Outreach/NPC/National-Provider-Calls-and-Events-Items/2016-01-20-MACRA.html.*

We considered both the comments submitted on the CY 2016 PFS proposed rule and the input provided at the listening session as we developed this proposal for data collection. When relevant, we discuss this stakeholder input below without distinguishing between comments on the proposed rule and input provided at the national listening session.

b. Data Collection Required To Accurately Value Global Packages

Resource-based valuation of individual physicians' services is a critical foundation for Medicare payment to physicians. It is essential that the RVUs under the PFS be based as closely and accurately as possible on the actual resources involved in furnishing the typical occurrence of specific services to make appropriate payment and preserve relativity among services. For global surgical packages, this requires using objective data on all of the resources used to furnish the services that are included in the package. Not having such data for some components may significantly skew relativity and create unwarranted payment disparities within the PFS.

The current valuations for many services valued as global packages are based upon the total package as a unit rather than by determining the resources used in furnishing the procedure and each additional service/visit and summing the results. As a result, we do not have the same level of information about the components of global packages as we do for other services. To value global packages accurately and relative to other procedures, we need accurate information about the resources—work, PEs and malpractice—used in furnishing the procedure, similar to what is used to determine RVUs for all services. In addition we need the same information on the post-operative services furnished in the global period (and pre-operative services the day before for 90-day global packages). Public comments about our proposal to value all global services as 0-day global services and pay separately for additional post-operative services when furnished indicated that there were no reliable data available on the value of the underlying procedure that did not also incorporate the value of the post-operative services, reinforcing our view that more data are needed across the board.

While we believe that most of the services furnished in the global period are visits for follow-up care, we do not have accurate information on the number and level of visits typically furnished because those billing for global services are not required to submit claims for post-operative visits. A May 2012 Office of Inspector General (OIG) report, entitled Cardiovascular Global Surgery Fees Often Did Not Reflect the Number of Evaluation and Management Services Provided (*http://oig.hhs.gov/oas/reports/region5/50900054.pdf*) found that for 202 of the 300 sampled cardiovascular global surgeries, the Medicare payment rates were based on a number of visits that did not reflect the actual number of services provided. Specifically, physicians provided fewer services than the visits included in the payment calculation for 132 global surgery services and provided more services than were included in the payment calculations for 70 services. Similar results were found in OIG reports entitled "Musculoskeletal Global Surgery Fees Often Did Not Reflect The Number Of Evaluation And Management Services Provided" (*http://oig.hhs.gov/oas/reports/region5/50900053.asp*) and "Review of Cataract Global Surgeries and Related Evaluation and Management Services, Wisconsin Physicians Service Insurance Corporation Calendar Year 2003, March 2007" (*http://oig.hhs.gov/oas/reports/region5/50600040.pdf*).

Claims data plays a major role in PFS rate-setting. Specifically, Medicare claims data is a primary driver in the allocation of indirect PE RVUs and MP RVUs across the codes used by particular specialties, and in making overall budget neutrality and relativity adjustments. In most cases, a claim must be filed for all visits. Such claims provide information such as the place of service, the type and, if relevant, the level of the service, the date of the service, and the specialty of the practitioner furnishing the services. Because we have not required claims reporting of visits included in global surgical packages, we do not have any of this information for the services bundled in the package.

In addition to the lack of information about the number and level of visits actually furnished, the current global valuations rely on crosswalks to E/M visits, based upon the assumption that the resources, including work, used in furnishing pre- and post-operative visits are similar to those used in furnishing E/M visits. We are unaware of any studies or surveys that verify this assertion. Although we generally value global packages using the same direct PE inputs as are used for the E/M services, for services for which the RUC recommendations include specific PE inputs in addition to those typically included for E/M services, we generally use the additional inputs in the global package valuation. Of note, when a visit included in a global package would use fewer resources than a comparable E/M service, the RUC generally does not include recommendations to decrease the PE inputs of the visit included in the global package, and we have not generally made comparable reductions. Another inconsistency with our current global package valuation approach is that even though we effectively assume that the E/M codes are appropriate for valuing pre- and post-operative services, the indirect PE inputs used for calculating payments for global services are based upon the specialty mix furnishing the global service, not the specialty mix of the physicians furnishing the E/M services, resulting in a different valuation for the E/M services contained in global packages than for separately billable E/M services. There is a critical need to obtain complete information if we are to value global packages accurately and in a way that preserves relativity across the fee schedule.

To meet the requirement under section 1848(c)(8)(B)(i) of the Act, we develop, through rulemaking, a process to gather information needed to value surgical services. Therefore, we are proposing a rigorous data collection effort that we believe would provide us the data needed to accurately value the 4,200 codes with a 10- or 90-day global period. Using our authority under sections 1848(c)(2)(M) and (c)(8)(B)(i) of the Act, we propose to gather the data needed to determine how to best structure global packages with post-operative care that is typically delivered days, weeks or months after the procedure and whether there are some procedures for which accurate valuation for packaged post-operative care is not possible. Finally, we believe these data would provide useful information to assess the resources used in furnishing pre- and post-operative care. To accurately do so, we need to know the volume and costs of the resources typically used. Although it may not be possible to gather all the necessary data and to complete the analysis required to re-value all of the codes currently valued as 10- or 90-day global packages by January 1, 2019, we believe the proposed data collection would provide the foundation for such valuations and would allow us to re-value, as appropriate, the surgical services on a flow basis, starting in rulemaking for CY 2019.

We are proposing a three-pronged approach to collect timely and accurate data on the frequency of, and inputs involved in furnishing, global services including the procedure and the pre-operative visits, post-operative visits, and other services for which payment is included in the global surgical payment. By analyzing these data, we would not only have the most comprehensive information available on the resources used in furnishing these services, but also would be able to determine the appropriate packages for such services. Specifically, the effort would include:

- Comprehensive claims-based reporting about the number and level of pre- and post-operative visits furnished for 10- and 90-day global services.
- A survey of a representative sample of practitioners about the activities involved in and the resources used in providing a number of pre- and post-operative visits during a specified, recent period of time, such as two weeks.
- A more in-depth study, including direct observation of the pre- and post-operative care delivered in a small number of sites, including some ACOs.

This work is critical to understanding and characterizing the work and other resources involved in furnishing services throughout the current global periods assigned to specific surgical procedures. The information collected and analyzed through the activities would be the first comprehensive look at the volume and level of services in a global period, and the activities and inputs involved in furnishing global services. The data from these activities would ultimately inform our revaluation of global surgical packages.

(1) Statutory Authority for Data Collection

As described above, section 1848(c)(8)(B)(i) of the Act requires us to develop, through rulemaking, a process to gather information needed to value surgical services from a representative sample of physicians. The statute requires that the collected information include the number and level of medical visits furnished during the global period and other items and services related to the surgery and furnished during the global period, as appropriate.

In addition, section 1848(c)(2)(M) of the Act, which was added to the Act by section 220 of the PAMA, authorizes the Secretary to collect or obtain information on resources directly or indirectly related to furnishing services for which payment is made under the PFS. Such information may be collected or obtained from any eligible professional or any other source. Information may be collected or obtained from surveys of physicians, other suppliers, providers of services, manufacturers, and vendors. That section also authorizes the Secretary to collect information through any other mechanism determined appropriate. When using information gathered under this authority, the statute requires the Secretary to disclose the information source and discuss the use of such information in the determination of relative values through notice and comment rulemaking.

As described above, to gain all the information that is needed to determine the appropriate packages for global services and to revalue those services, we need to conduct a comprehensive study on the resources used in furnishing such services. Through such a study, we would have much more robust data to use in valuation than has been typically available. We anticipate that such efforts would inform how to more regularly collect data on the resources used in furnishing physicians' services. To the extent that such mechanisms prove valuable, they may be used to collect data for valuing other services. To achieve this significant data collection, we are proposing to collect data under the authority of both section 1848(c)(8)(B) and (c)(2)(M) of the Act.

(2) Claims-Based Data Collection

This section describes our proposal for claims-based data collection that would be applicable to 10- and 90-day global services furnished on or after January 1, 2017, including who would be required to report, what they would be required to report, and how reports would be submitted.

(a) Information To Be Reported

A key element of claims-based reporting is using codes that appropriately reflect the services furnished. In response to the comment solicitation in the CY 2016 PFS proposed rule and in the January 2016 listening session, we received numerous recommendations for the information to be reported on claims. The most frequently recommended approach was for practitioners to report the existing CPT code for follow-up visits included in the surgical package (CPT 99024—Postoperative follow-up visit, normally included in the surgical package, to indicate that an E/M service was performed during a postoperative period for a reason(s) related to the original procedure). Others suggested using this code for outpatient visits and using length of stay data for estimating the number of inpatient visits during the global period. In response to our concerns that CPT code 99024 would provide only the number of visits and not the level of visits as required by the statute, one commenter suggested using modifiers in conjunction with CPT code 99024 to indicate the level of the visit furnished. Others recommended using existing CPT codes for E/M visits to report post-operative care. One commenter suggested that CMS analyze data from a sample of large systems and practices that are using electronic health records that require entry of some CPT code for every visit to capture the number of post-operative visits. After noting that the documentation requirements and PEs required for post-operative visits differ from those of E/M visits outside the global period, one commenter encouraged us to develop a separate series of codes to capture the work of the post-operative services and to measure, not just estimate, the number and complexity of visits during the global period.

Other commenters opposed the use of a new set of codes or the use of modifiers to report post-operative visits. Commenters also noted several issues for us to consider in developing data collection mechanisms, including that many post-operative services do not have CPT codes to bill separately, that surgeons perform a wide range of collaborative care services, and that patient factors, including disease severity and comorbidities, influence what post-operative care is furnished.

To assist us in determining appropriate coding for claims-based reporting, we added a task to the RAND contract for developing a model to validate the RVUs in the PFS, which was awarded in response to a requirement in the Affordable Care Act. Comments that we received on RAND's report suggested the models did not adequately address global surgery services due to the lack of available data on included visits. Therefore, we modified the RAND contract to include the development of G-codes that could be used to collect data about post-surgical follow-up visits on Medicare claims for valuing global services under MACRA and so that this time could be included in the model for validating RVUs.

To inform its work, RAND conducted interviews with surgeons and other physicians/non-physician practitioners (NPP) who provide post-operative care. A technical expert panel (TEP), convened by RAND, reviewed the findings of the interviews and provided input on how to best capture care provided in the post-operative period on claims.

In summarizing the input from the interviews and the TEP, RAND indicated that several considerations were important in developing a claims-based method for capturing post-operative services. First, a simple system to facilitate reporting was needed. Since it was reported that a majority of post-operative visits are straightforward, RAND found that a key for any proposed system is identifying the smaller number of complex post-operative visits. Another consideration for RAND was not using the existing CPT E/M structure to capture postoperative care because of concerns that E/M codes are inadequately designed to capture the full scope of post-operative care and that using such codes might create confusion. Another consideration was that the TEP was most enthusiastic about a set of codes that used site of care, time, and complexity to report visits. RAND also believed it was important to distinguish—particularly in the inpatient setting—between circumstances where a surgeon is providing primary versus secondary management of a patient. Finally, a mechanism for reporting the postoperative care occurs outside of in-person visits and by clinical staff was needed. RAND noted that in the inpatient setting in particular, surgeons spend considerable time reviewing test results and coordinating care with other practitioners.

After reviewing various approaches, RAND recommended a set of time-based, post-operative visit codes that could be used for reporting care provided during the post-operative period.

The recommended codes are distinguished by the setting of care and whether they are furnished by a physician/NPP or by clinical staff. All codes are intended to be reported in 10-minute increments. A copy of the report is available available on the CMS Web site under downloads for the CY 2017 PFS proposed rule with comment period at *http://www.cms.gov/physicianfeesched/downloads/*.

Based upon the work done by RAND, we are proposing the following codes be used for reporting on claims the services actually furnished but not paid separately because they are part of global packages. No separate payment would be made for these codes.

TABLE 9—PROPOSED GLOBAL SERVICE CODES

Inpatient	GXXX1	Inpatient visit, typical, per 10 minutes, included in surgical package.
	GXXX2	Inpatient visit, complex, per 10 minutes, included in surgical package.
	GXXX3	Inpatient visit, critical illness, per 10 minutes, included in surgical package.
Office or Other Outpatient	GXXX4	Office or other outpatient visit, clinical staff, per 10 minutes, included in surgical package.
	GXXX5	Office or other outpatient visit, typical, per 10 minutes, included in surgical package.
	GXXX6	Office or other outpatient visit, complex, per 10 minutes, included in surgical package.
Via Phone or Internet	GXXX7	Patient interactions via electronic means by physician/NPP, per 10 minutes, included in surgical package.
	GXXX8	Patient interactions via electronic means by clinical staff, per 10 minutes, included in surgical package.

(i) Coding for Inpatient Global Service Visits

Our coding proposal includes three codes for reporting inpatient pre- and post-operative visits that distinguish the intensity involved in furnishing the services. The typical inpatient visit would be reported using HCPCS code GXXX1, Inpatient visit, typical, per 10 minutes, included in surgical package. The activities listed in Table 10 are those that RAND recommended to be reported as a typical visit. Under our proposal, visits that involve any combination or number of the services listed in Table 10 would be reported using GXXX1. Based on the findings from the interviews and the TEP, RAND reports that the vast majority of inpatient post-operative visits would be expected to be reported using GXXX1.

TABLE 10—ACTIVITIES INCLUDED IN TYPICAL VISIT (GXXX1 & GXXX5)

Review vitals, laboratory or pathology results, imaging, progress notes
Take interim patient history and evaluate post-operative progress
Assess bowel function
Conduct patient examination with a specific focus on incisions and wounds, post-surgical pain, complications, fluid and diet intake
Manage medications (for example, wean pain medications)
Remove stitches, sutures, and staples
Change dressings
Counsel patient and family in person or via phone
Write progress notes, post-operative orders, prescriptions, and discharge summary
Contact/coordinate care with referring physician or other clinical staff
Complete forms or other paperwork

Inpatient pre- and post-operative visits that are more complex than typical visits but do not qualify as critical illness visits would be coded using GXXX2 (Inpatient visit, complex, per 10 minutes, included in surgical package). To report this code, the practitioner would be required to furnish services beyond those included in a typical visit and have documentation that indicates what services were provided that exceeded those included in a typical visit. Some circumstances that might merit the use of the complex visit code are secondary management of a critically ill patient where another provider such as an intensivist is providing the primary management, primary management of a particularly complex patient such as a patient with numerous comorbidities or high likelihood of significant decline or death, management of a significant complication, or complex procedures outside of the operating room (For example, significant debridement at the bedside).

The highest level of inpatient pre- and post-operative visits, critical illness visits (GXXX3—Inpatient visit, critical illness, per 10 minutes, included in surgical package) would be reported when the physician is providing primary management of the patient at a level of care that would be reported using critical care codes if it occurred outside of the global period. This involves acute impairment of one or more vital organ systems such that there is a high probability of imminent or life threatening deterioration in the patient's condition.

Similar to how time is now counted for the existing CPT critical care codes, all time spent engaged in work directly related to the individual patient's care would count toward the time reported with the inpatient visit codes; this includes time spent at the immediate bedside or elsewhere on the floor or unit, such as time spent with the patient and family members, reviewing test results or imaging studies, discussing care with other staff, and documenting care.

(ii) Coding for Office and Other Outpatient Global Services Visits

Our proposal includes three codes that would be used for reporting post-operative visits in the office or other outpatient settings. For these three codes, time would be defined as the face-to-face time with patient, which reflects the current rules for time-based outpatient codes.

Under our proposal, GXXX4 (Office or other outpatient visit, clinical staff, per 10 minutes, included in surgical package) would be used for visits in which the clinical care is provided by clinical staff.

GXXX5 (Office or other outpatient visit, typical, per 10 minutes, included in surgical package) would be used for reporting any combination of activities in Table 10. Based on the findings from the interviews and the TEP, RAND reports that the vast majority of office or other outpatient visits would be expected to be reported using the GXXX5 code.

Accordingly, we would expect the office or other outpatient visit code, complex, GXXX6 (Office or other outpatient visit, complex, per 10 minutes, included in surgical package), to be used infrequently. Examples of when it might be used include management of a particularly complex patient such as a patient with numerous comorbidities or high likelihood of dying, management of a significant complication, or management or discussion of a complex diagnosis (For example, new cancer diagnosis, high risk of mortality). Practitioners would include documentation in the medical record as to what services were provided that exceeded those included in a typical visit.

Only face-to-face time spent by the practitioner with the patient and their family members would count toward the time reported with the office visit codes. Therefore, even though the codes for both inpatient and outpatient settings use the same time increment, the services that are included differ by setting, consistent with the variation in existing coding conventions.

(iii) Coding for Services Furnished Via Electronic Means

Services that are provided via phone, the internet, or other electronic means outside the context of a face-to-face visit would be reported using GXXX7 when furnished by a practitioner and GXXX8 when furnished by clinical staff. We are proposing that practitioners would not report these services if they are furnished the day before, the day of, or the day after a visit as we believe these would be included in the pre- and post-service activities in the typical visit. However, we are proposing that these codes be used to report non-face-to-face services provided by clinical staff prior to the primary procedure since global surgery codes are typically valued with assumptions regarding pre-service clinical labor time. Given that some practitioners have indicated that services they furnish commonly include activities outside the face-to-face service, we believe it is important to capture information about those activities in both the pre- and post-service periods. We believe these requirements to report on clinical labor time are consistent with and no more burdensome than those used to report clinical labor time associated with chronic care management services, which similarly describe care that takes place over more than one patient encounter.

In addition, for services furnished via interactive telecommunications that meet the requirements of a Medicare telehealth service visit, the appropriate global service G-code for the services should be reported with the GT modifier to indicate that the service was furnished "via interactive audio and video telecommunications systems."

(iv) Benefits of G-Codes

One commenter indicated that the documentation requirements and PEs for post-operative visits differ from those of other E/M visits, and encouraged us to develop a separate series of codes to capture the work of the post-operative services and to measure, not just estimate, the number and complexity of visits during the global period. Others opposed the use of a new set of codes or the use of modifiers to collect information on post-operative visits. After considering the RAND report, the comments and other stakeholder input that we have received, and our needs for data to fulfill our statutory mandate and to value surgical services appropriately, we are proposing this new set of codes because we believe it provides us the most robust data upon which to determine the most appropriate way and amounts to pay for PFS surgical services. We believe that the codes being proposed would provide data of the kind that can reasonably collected through claims data and that reflect what we believe are key issues in the post-operative care where the service is provided, who furnishes the service, its relative complexity, and the time involved in the service.

We seek public comments about all aspects of these codes, including the nature of the services described, the time increment, and any other areas of interest to stakeholders. We are particularly interested in any pre- or post-operative services furnished that could not be appropriately captured by these codes. Although RAND developed this set of codes to collect data on post-operative services, we are proposing to also use such codes to collect data on pre-operative services. We are seeking comments on whether the codes discussed above are appropriate for collecting data on pre-operative services or whether additional codes should be added to distinguish in the data collected the resources used for pre-operative services from those used for post-operative services. We also seek comment on any activities that should be added to the list of activities in Table 10 to reflect typical pre-operative visit activities.

(v) Alternative Approach to Coding

As noted above, many stakeholders expressed strong support for the use of CPT code 99024 (Postoperative follow-up visit, normally included in the surgical package, to indicate that an evaluation and management service was performed during a postoperative period for a reason(s) related to the original procedure) to collect data on post-operative care. Stakeholders suggest that practitioners are familiar with this existing CPT code and the burden on practitioners would be minimized by only having to report that a visit occurred, not the level of the visit. We do not believe that this code alone would provide the information that we need for valuing surgical services nor do we believe it alone can meet the statutory requirement that we collect data on the number and level of visits because it does not provide any information beyond the number of visits. Although we are proposing to use the G-codes detailed above to measure pre- and post-operative visits, given the strong support that many stakeholders have for the use of CPT code 99024, we are soliciting comments specifically on how we could use this code to capture the statutorily required data on the number and level of visits and the data that we would need to value global services in the future.

Some have suggested using CPT code 99024 with modifiers to indicate to which of the existing levels of E/M codes the visit corresponds. As outlined in the RAND report, E/M visits may not accurately capture what drives greater complexity in post-operative visits. E/M billing requirements are built upon complexity in elements such as medical history, review of systems, family history, social history, and how many organ systems are examined. In the context of a post-operative visit, many of these elements may be irrelevant. RAND also noted that there was significant concern from interviewees and the expert panel about documentation that is required for reporting E/M codes. Specifically, they argued that documentation requirements for surgeons to support the relevant E/M visit code would place undue administrative burden on surgeons. RAND reported that many surgeons currently use minimal documentation when they provide a postoperative visit. Moreover, to value surgical packages accurately we need to understand the activities involved in furnishing post-operative care and as discussed above, we lack information that would demonstrate that activities involved in post-operative care are similar to those in E/M services. In addition, the use of modifiers to report levels of services is more difficult to operationalize than using unique HCPCS codes. However, we would be interested in whether, and if so, why, practitioners would find it easier to report CPT code 99024 with modifiers corresponding to the proposed G-code levels rather than the new G-codes, as proposed. We are also seeking comment on whether practitioners would find it difficult to use this for pre-operative visits since the CPT code descriptor specifically defines it as a "post-operative follow-up" service.

We are also seeking comment on whether time of visits could alone be a proxy for the level of visit. If pre- and post-operative care varies only by the time the practitioner spends care so that time could be a proxy for complexity of the service, then we could use the reporting of CPT code 99024 in 10-minute increments to meet the statutory requirement of collecting claims-based data on the number and level of visits. In addition to comments on whether time is an accurate proxy for level of visit, we are seeking comment on the feasibility and desirability of reporting CPT 99024 in 10-minute increments.

c. Reporting of Claims

We propose that the G-codes detailed above would be reported for services related to and within 10- and 90-day global periods for procedures furnished on or after January 1, 2017. Services related to the procedure furnished following recovery and otherwise within the relevant global period would be required to be reported. These codes would be included on claims filed through the usual process. Through this mechanism, we would collect all of the information reported on a claim for services, including information about the practitioner, service furnished, date of service, and the units of service. By not imposing special reporting requirements on the reporting of these codes, we intend to allow practitioners the flexibility to report the services on a rolling basis as they are furnished or to report all of the services on one claim once all have been furnished, as long as the filed claims meet the requirements for filing claims. As with all other claims, we would expect the patient's medical record to include documentation of the services furnished. Documentation that would be expected is an indication that a visit occurred or a service was furnished and sufficient information to determine that the appropriate G-code was reported.

We are not proposing any special requirements for inclusion of additional data on claims that could be used for linking the post-operative care furnished to a particular service. To use the data reported on post-operative visits for analysis and valuation, we will link the data reported on post-operative care to the related procedure using date of service, practitioner, beneficiary, and diagnosis. We believe this approach to matching will allow us to accurately link the preponderance of G-codes to the related procedure. However, we solicit comment on the extent to which post-operative care may not be appropriately linked to related procedures whether we should consider using additional variables to link these aspects of the care, and whether additional data should be required to be reported to enable a higher percentage of matching.

d. Special Provisions for Teaching Physicians

We are seeking comment on whether special provisions are needed to capture the pre- and post-operative services provided by residents in teaching settings. If the surgeon is present for the key portion of the visit, should the surgeon report the joint time spent by the resident and surgeon with the patient? If the surgeon is not present for the key portion of the visit, should the resident report the service? If we value services without accounting for services provided by residents that would otherwise be furnished by the surgeon in non-teaching settings, subsequent valuations based upon the data we collect may underestimate the resources used, particularly for the types of surgeries typically furnished in teaching facilities. However, there is also a risk of overvaluing services if the reporting includes services that are provided by residents when those services would otherwise be furnished by a physician other than the surgeon, such as a hospitalist or intensivist, and as such, should not be valued in the global package.

e. Who Reports

In both the comments on the CY 2016 proposed rule and in the national listening session, there was a great deal of discussion regarding the challenges that we are likely to encounter in obtaining adequate data to support appropriate valuation. Some indicated that a broad sample and significant cooperation from physicians would be necessary to understand what is happening as part of the global surgical package. One commenter suggested that determining a representative sample would be difficult and, due to the variability related to the patient characteristics, it would be easier to have all practitioners report. Many suggested that we conduct an extensive analysis across surgical specialties with a sample that is representative of the entire physician community and covers the broad spectrum of the various types of physician practice to avoid problems that biased or inadequate data collection would cause. Suggestions of factors to account for in selecting a sample include specialty, practice size (including solo practices), practice setting, volume of claims, urban, rural, type of surgery, and type of health care delivery systems. Another commenter pointed out that small sample sizes may lead to unreliable data. On the other hand, some commenters stated that requiring all practitioners to report this information is unreasonable and would be an insurmountable burden. A participant acknowledged that it would be difficult for practitioners to report on only certain procedures, while another stated that this would not be an administrative burden.

After considering the input of stakeholders, we are proposing that any practitioner who furnishes a procedure that is a 10- or 90-day global report the pre- and post-operative services furnished on a claim using the codes proposed above. We agree with stakeholders that it is necessary to obtain data from a broad, representative sample across specialties, geographic location, and practice size, practice model, patient acuity, and differing practice patterns. However, as we struggled to develop a sampling approach that would result in statistically reliable and valid data, it became apparent that we do not have adequate information about how post-operative care is delivered, how it varies and, more specifically, what drives variation in post-operative care. In its work to develop the coding used for its study, RAND found a range of opinions on what drives variation in post-operative care. (The report is available on the CMS Web site under downloads for the CY 2017 PFS proposed rule with comment period at *http://www.cms.gov/physicianfeesched/downloads/*.) Without information on what drives variation in pre- and post-operative care, we would have to speculate about the factors upon which to base a sample or assume that the variation in such care results from the same variables as are frequently identified for explaining variation in health care and clinical practice. In addition, we have concerns about whether a sample could provide sufficient volume to value accurately the global package, except in the case of a few high-volume procedures.

In addition to concerns about achieving an appropriate, sufficient, and unbiased representative sample of practitioners, we have significant operational concerns with collecting data from a limited sample of practitioners or on a limited sample of services. These include how to gain sufficient information on practitioners to sufficiently stratify the sample, how to identify the practitioners who must report, determining which services, and for those who practice in multiple settings and/or with multiple groups in which settings the practitioner would report. Establishing the rules to govern which post-operative care should be reported for which procedures would be challenging for us to develop for a random sample and difficult for physicians to apply.

With the limited time between the issuance of the CY 2017 PFS final rule with comment period and the beginning of reporting on January 1st, it would be challenging to make sure that affected practitioners are aware of the requirement to report and have an ability to determine which post-operative care to report. If, instead, we require all practitioners to report, we can take a uniform approach to notifying practitioners. The national medical and coding organizations are routinely relied upon by practitioners for information on new coding and billing requirements and play a major role in the expeditious adoption of new coding or billing requirements. Similarly, adjustments to software used for medical records and coding are made by national organizations. We have concerns that if this requirement is only applied to a small segment of practitioners that these organizations will not be able to ensure that the affected practitioners are aware and easily able to comply with the requirements.

The more robust the reported data, the more accurate our ultimate valuations can be. Given the importance of data on visits in accurate valuations for global packages, we believe that collecting data on all pre- and post-operative visits in the global period is the best way to accurately value surgical procedures with global packages.

We recognize that reporting of all pre- and post-operative visits would require submission of additional claims by those practitioners furnishing global services, but we believe the benefits of accurate data for valuation of services merits the imposition of this requirement. By using the claims system to report the data, we believe the additional burden is minimized. Stakeholders have reported that many practitioners are already required by their practice or health care system to report a code for each visit for internal control purposes and some of these systems already submit claims for these services, which are denied. For these practices, the additional burden would be minimal. We believe that requiring only some physicians to report this information, or requiring reporting for only some services, could actually be more burdensome to physicians than requiring this information from all physicians on all services because of the additional steps necessary to determine whether a report is required for a particular service and adopting a mechanism to assure that data is collected and reported when required. Moreover, we believe the challenges with implementing a limited approach at the practice level as compared to a requirement for all global services would result in less reliable data being reported.

As we analyze the data collected and make decisions about valuations, we would reassess the data needed and what should be required from whom. Under section 1848(c)(8)(B)(ii) of the Act, we are required to reassess every 4 years whether continued collection of these data is needed. However, we can modify through rulemaking what data is collected at any time, as appropriate. By collecting data on all procedures with a 10- or 90-day global package, we would have the information to assess whether the post-operative care furnished varies by factors such as specialty, geography, practice setting, and practice size, and thus, the information needed for a selection of a representative sample. By initially collecting information from all practitioners that furnish surgical services, we believe we would be able to reduce required reporting in the future if we find that adequate information can be obtained by selective reporting. Without the broader set of data we would not be able to evaluate the variability of pre- and post-operative care in order to identify a useful targeted data collection.

While section 1848(c)(8)(B) of the Act requires us to collect data from a representative sample of physicians on the number and level of visits provided during the global period, it does not prohibit us from collecting data from a broad set of physicians. In addition, section 1848(c)(2)(M) of the Act authorizes the collection of data from a wide range of physicians. Given the benefits of more robust data, including avoiding sample bias, obtaining more accurate data, and facilitating operational simplicity, we believe collecting data on all post-operative care initially is the best way to undertake an accurate valuation of surgical services in the future.

(1) Survey of Practitioners

We agree with commenters that we need more information than is currently provided on claims and that we should utilize a number of different data sources and collection approaches to collect the data needed to assess and revalue global surgery services. In addition to the claims-based reporting, we are proposing to survey a large, representative sample of practitioners and their clinical staff in which respondents would report information about approximately 20 discrete pre-operative and post-operative visits and other global services like care coordination and patient training. The proposed survey would produce data on a large sample of pre-operative and post-operative visits and is being designed so that we could analyze the data collected in conjunction with the claims-based data that we would be collecting. We expect to obtain data from approximately 5,000 practitioners.

We have contracted with RAND to develop and, if our proposal is finalized, conduct this survey. RAND would also assist us in analyzing data collected under this survey and the claims-based data. While the primary data collection would be via a survey instrument, RAND would conduct semi-structured interviews and direct observations of data in a small number of pilot sites to inform survey design, validate survey results, and collect information that is not conducive to survey-based reporting.

Our proposed sampling approach would sample practitioners rather than for procedures or visits to streamline survey data collection and minimize respondent burden. Specifically, we propose to representative and random sample from a frame of providers who billed Medicare for more than a minimum threshold of surgical procedures with a 10- or 90-day global period (for example, 200 procedures) in the most recent available prior year of claims data. We expect to survey approximately 5,000 practitioners, stratified by specialty, geography, and practice type. Based upon preliminary analysis we believe this number of participants will allow us to collect information on post-operative care following the full range of CPT level-2 surgical procedure code groups. A smaller sample size would reduce the precision of estimates from the survey and more importantly risk missing important differences in post-operative care for specific specialties or following different types of surgical procedures. We expect a response rate in excess of 50 percent.

We are not proposing that respondents report on the entire period of post-operative care for individual patients, as a 90-day follow-up window (for surgeries currently with a 90-day global period) is too long to implement practically in this study setting and would be more burdensome to practitioners. Instead, we propose to collect information on a range of different post-operative services resulting from surgeries furnished by the in-sample practitioner prior to or during a fixed reporting period.

Each sampled practitioner will be assigned to a specified and brief (for example, 2-week) reporting period. Given the proposed overall data collection period, the selected sample of providers will be randomly divided into 6 subsets within each specialty, each of which will be assigned to a specified reporting period. Practitioners will be asked to describe 20 post-operative visits furnished to Medicare beneficiaries or other patients during the reporting period. The information collected through the survey instrument, which will be developed based upon direct observation and discussions in a small number of pilot sites, will include contextual information to describe the background for the post-operative care, including, for example:

- Procedure codes(s) and date of service for procedure upon which the global period is based.
- Procedure place of service (type).
- Whether or not there were complications during or after the procedure.
- The number in sequence of the follow-up visit (for example, the first visit after the procedure).

The survey instrument will also collect information on the visit in question including, for example:

- Which level of visit using the finalized no-pay codes.
- Specific pre-service, face-to-face, and post-service activities furnished during the visit.
- Times for each activity.
- Identify who performed each activity (physician or other practitioner).
- PE components used during the visit, for example supplies like surgical dressings and clinical staff time.

Finally, the instrument will ask respondents to report other prior or anticipated care furnished to the patient by the practice outside of the context of a post-operative visit, for example non-face-to-face services.

The survey approach will complement the claims data collection by collecting detailed information on the activities, time, intensity, and resources involved in delivering global services. The resulting visit-level survey data would allow us to explore in detail the variation in activities, time, intensity, and resources associated with global services within and between physicians and procedures, and would help to validate the information gathered through claims. A summary of the work that RAND would be doing is available on the CMS Web site under downloads for the CY 2017 PFS proposed rule with comment period at *http://www.cms.gov/physicianfeesched/downloads/*.

(2) Required Participation in Data Collection

Using the authority we are provided under sections 1848(c)(8) and 1848(c)(2)(M) of the Act, we are proposing to require all practitioners who furnish a 10- or 90-day global service to submit a claim(s) providing information on all services furnished within the relevant global service period in the form and manner described below, beginning with surgical or procedural services furnished on or after January 1, 2017. We are also proposing to require participation by practitioners selected for the broad-based survey through which we are proposing to gather additional data needed to value surgical services, such as the clinical labor and equipment involved that cannot be efficiently collected on claim (see below).

Given the importance of the proposed survey effort, making sure that we get valid data is critical. By eliminating the bias that would be associated with using only data reported voluntarily, we believe we will get more accurate and representative data. In addition to the potential bias inherent in voluntary surveys, we are concerned that relying on voluntary data reporting would limit the adequacy of the volume of data we obtain, will require more effort to recruit participation, and may make it impossible to obtain data for valuation for CY 2019 as required by the statute.

Based on our previous experience with requesting voluntary cooperation in data collection activity, voluntary participation poses a significant challenge in data collection. Specifically, the Urban Institute's work (under contract with us) to validate work RVUs by conducting direct observation of the time it took to furnish certain elements of services paid under the physician fee schedule provides evidence of this challenge. (See *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Downloads/RVUs-Validation-Urban-Interim-Report.pdf* for an interim report that describes challenges in securing participation in voluntary data collection.) Similarly, we routinely request invoices on equipment and supplies that are used in furnishing services and often receive no more than one invoice. These experiences support the idea that mandatory participation in data collection activities is essential if we are to collect valid and unbiased data.

Section 1848(a)(9) of the Act authorizes us, through rulemaking, to withhold payment of up to 5 percent of the payment for services on which the practitioner is required to report under section 1848(c)(8)(B)(i) of the Act until the practitioner has completed the required reporting. Some commenters opposed the imposition of this payment withhold, and others said it was too large of a penalty. While we believe this is a way to encourage practitioners to report on claims the information we propose to require on care that is furnished in the global period, we are not proposing to implement this option at this time. We believe that requiring physicians to report the information on claims, combined with the incentive to report complete information so that we can make appropriate revisions when we revalue payments for global surgical services, would result in compliance with the reporting requirements. However, we note that if we find that compliance with required claims-based reporting is not acceptable, we would consider in future rulemaking imposing up to a 5 percent payment withhold as authorized by the statute.

Consistent with the requirements of section 1848(c)(2)(M) of the Act, should the data collected under this requirement be used to determine RVUs, we will disclose the information source and discuss the use of such information in such determination of relative values through future notice and comment rulemaking.

(3) Data Collection From Accountable Care Organizations (ACOs)

We are particularly interested in knowing whether physicians and practices affiliated with ACOs expend greater time and effort in providing post-operative global services in keeping with their goal of improving care coordination for their assigned beneficiaries. ACOs are organizations in which practitioners and hospitals voluntarily come together to provide high-quality and coordinated care for their patients. Because such organizations share in the savings realized by Medicare, their incentive is to minimize post-operative visits while maintaining high quality post-operative care for patients. In addition, we believe that such organizations offer us the opportunity to gain more in-depth information about delivery of surgical services.

We propose to collect primary data on the activities and resources involved in delivering services in and around surgical events in the ACO context by surveying a small number of ACOs (Pioneer and Next Generation ACOs).

Similar to the approach of the more general practitioner survey, this effort would begin with an initial phase of primary data collection using a range of methodologies in a small number of ACOs; development, piloting, and validation of an additional survey module specific to ACOs. A survey of practitioners participating in approximately 4 to 6 ACOs using the survey instrument along with the additional ACO-specific module will be used to collect data from on pre- and post-operative visits.

(4) Conclusion

We recognize that the some of the data collection activity proposed here varies greatly from how the data is currently gathered to support PFS valuations for global surgery services. However, we believe the proposed claims-based data collection is generally consistent with how claims data is reported for other kinds of services paid under the PFS. We believe that the authority and requirements included in the statute through the MACRA and PAMA were intended to expand and enhance data that might be available to enhance the accuracy of PFS payments. Because these are new approaches to collecting data and in an area—global surgery—where very little data has previously been collected, we cannot describe exactly how this information would be used in valuing services. What is clear is that the claims-based data would provide information parallel to the kinds of claims-data used in developing RVUs for other PFS services and that by collecting these data, we would know far more than we do now about how post-operative care is delivered and gain insight to support appropriate packaging and valuation. We would include any revaluation proposals based on these data in subsequent notice and comment rulemaking.

E. Improving Payment Accuracy for Primary Care, Care Management, and Patient-Centered Services

1. Overview

In recent years, we have undertaken ongoing efforts to support primary care and patient-centered care management within the PFS as part of HHS' broader efforts to achieve better care, smarter spending and healthier people through delivery system reform. We have recognized the need to improve payment accuracy for primary care and patient-centered care management over several years, especially beginning in the CY 2012 PFS proposed rule (76 FR 42793) and continuing in each subsequent year of rulemaking. In the CY 2012 proposed rule, we acknowledged the limitations of the current code set that describes evaluation & management (E/M) services within the PFS. For example, E/M services represent a high proportion of PFS expenditures but have not been recently revalued to account for significant changes in the disease burden of the Medicare patient population and changes in health care practice that are underway, to meet the current population's health care needs. These trends in the Medicare population and health care practice have been widely recognized in the provider community and by health services researchers and policymakers alike.[1] We believe the focus of the health care system has shifted to delivery system reforms, such as patient-centered medical homes, clinical practice improvement, and increased investment in primary and comprehensive care management/coordination services for chronic and other conditions. This shift requires centralized management of patient needs and extensive care coordination among practitioners and providers (often on a non-face-to-face basis across an extended period of time). In contrast, the current CPT code set is designed with an overall orientation to pay for discrete services and procedural care as opposed to ongoing primary care, care management and coordination, and cognitive services. It includes thousands of separately paid, individual codes, most of which describe highly specialized procedures and diagnostic tests, while there are relatively few codes that describe care management and cognitive services. Further, in the past, we have not recognized as separately payable many existing CPT codes that describe care management and cognitive services, viewing them as bundled and paid as part of other services including the broadly drawn E/M codes that describe face-to-face visits billed by physicians and practitioners in all specialties.

This has resulted in minimal service variation for ongoing primary care, care management and coordination, and cognitive services relative to other PFS services, and in potential misvaluation of E/M services under the PFS (76 FR 42793). Some stakeholders believe that there is substantial misvaluation of physician work within the PFS, and that the current service codes fail to capture the range and intensity of nonprocedural physician activities (E/M services) and the "cognitive" work of certain specialties (*http://www.nejm.org/doi/full/10.1056/NEJMp1600999#t=article*).

Recognizing the inverse for specialties that furnish other kinds of services, MedPAC has noted that the PFS allows some specialties to more easily increase the volume of services they provide (and therefore their revenue from Medicare) relative to other specialties, particularly those that spend most of their time providing E/M services. (MedPAC March 2015 Report to the Congress, available at *http://www.medpac.gov/-documents-/reports*). We agree with this analysis, and we recognize that the current set of E/M codes limits Medicare's ability under the PFS to appropriately recognize the relative resource costs of primary care, care management/coordination and cognitive services relative to specialized procedures and diagnostic tests.

In recent years, we have been engaged in an ongoing incremental effort to update and improve the relative value of primary care, care management/coordination, and cognitive services within the PFS by identifying gaps in appropriate payment and coding. These efforts include changes in payment and coding for a broad range of PFS services. This effort is particularly vital in the context of the forthcoming transition to the Merit-Based Incentive Payment System (MIPS) and Alternative Payment Models (APMs) incentives under The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10, enacted April 16, 2015), since MIPS and many APMs will adopt and build on PFS coding, RVUs and PFS payment as their foundation.

In CY 2013, we began by focusing on post-discharge care management and transition of beneficiaries back into the community, establishing new codes to pay separately for transitional care management (TCM) services. Next we finalized new coding and separate payment beginning in CY 2015 for chronic care management (CCM) services provided by clinical staff. Most recently, in the CY 2016 PFS proposed rule (80 FR 41708 through 41711), we solicited public comments on three additional policy areas of consideration: (1) Improving payment for the professional work of care management services through coding that would more accurately describe and value the work of primary care and other cognitive specialties for complex patients (for example, monthly timed services including care coordination, patient/caregiver education, medication management, assessment and integration of data, care planning); (2) establishing separate payment for collaborative care, particularly, how we might better value and pay for robust inter-professional consultation, between primary care physicians and psychiatrists (developing codes to describe and provide payment for the evidence-based psychiatric collaborative care model (CoCM), and between primary care physicians and other (non-mental health) specialists; and (3) assessing whether current PFS payment for CCM services is adequate and whether we should reduce the administrative burden associated with furnishing and billing these services.

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[1] See, for example, *http://content.healthaffairs.org/content/25/5/w378.full*; *http://www.commonwealthfund.org/publications/issue-briefs/2008/feb/how-disease-burden-influences-medication-patterns-for-medicare-beneficiaries—implications-for-polic*; *http://www.hhs.gov/ash/about-ash/multiple-chronic-conditions/index.html*; *http://www.nejm.org/doi/full/10.1056/NEJMp1600999#t=article*; *https://www.pcpcc.org/about*; *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/MACRA-MIPS-and-APMs.html*.

In the CY 2016 PFS final rule with comment period (80 FR 70919 through 70921), we summarized the many public comments we received in response to last year's comment solicitation. Instead of the specific policies we sought comment on, several commenters recommended an overhaul and complete revaluation of the E/M codes through a major research initiative akin to that undertaken when the PFS was first established. Many other commenters recommended that, until a major research initiative could be conducted to fully address the deficiencies in the current E/M code set, CMS should make separate payment under Medicare for a number of existing CPT codes to improve payment in the areas in which we solicited comments, including the codes used to describe complex CCM services (CPT codes 99487 and 99489). Other commenters also suggested that care management services may be beneficial to a number of other patient populations in addition to those transitioning into the community from an inpatient setting and those with multiple chronic conditions.

Also in response to our CY 2016 comment solicitation, the AMA restructured its existing CPT/RUC workgroup on these issues and convened the relevant individual specialty societies to develop new CPT coding that would address these issues. We understand that these efforts are ongoing, and that at this time, two sets of new codes are scheduled to be included in the CY 2018 CPT code set in response to our 2016 comment solicitation. One is a set of new codes describing services furnished under the psychiatric CoCM and the other is a code for assessment and care planning services for patients with cognitive impairment. Several stakeholders have urged us to facilitate Medicare payment for these and other new primary care, care management, and cognitive services sooner than CY 2018 by proposing payment using G-codes for CY 2017.

In response to our comment solicitation in the CY 2016 proposed rule, MedPAC commented that the PFS is an ill-suited payment mechanism for primary care and cognitive care generally. MedPAC recommended that Congress replace the expired Primary Care Incentive Payment (PCIP) with a capitated payment mechanism and expressed preference for codes like CCM that are beneficiary-centered and do not pay for each distinct care coordination activity.

Finally, many public commenters recommended a number of modifications to the current CCM payment rules. According to many commenters, current payment does not cover the cost of furnishing these services, and therefore, the codes are underutilized. As referenced in section II.E.3 on improving access and payment for CCM services, our assessment of claims data for CY 2015 for CPT code 99490 suggests that CCM services may be underutilized relative to the intended eligible patient population.

After considering the commenters' perspective and recommendations, as well as monitoring the ongoing efforts at the AMA/RUC and CPT to respond with new/revised coding, for CY 2017 we are proposing a number of changes to coding and payment policies under the PFS. These proposals are intended to accomplish the following:

- Improve payment for care management services provided in the care of beneficiaries with behavioral health conditions (including services for substance use disorder treatment) through new coding, including three codes used to describe services furnished as part of the psychiatric CoCM and one to address behavioral health integration more broadly.
- Improve payment for cognition and functional assessment, and care planning for beneficiaries with cognitive impairment.
- Adjust payment for routine visits furnished to beneficiaries whose care requires additional resources due to their mobility-related disabilities.
- Recognize for Medicare payment the additional CPT codes within the Chronic Care Management family (for Complex CCM services) and adjust payment for the visit during which CCM services are initiated (the initiating CCM visit) to reflect resources associated with the assessment for, and development of, a new care plan.
- Recognize for Medicare payment CPT codes for non-face-to-face Prolonged E/M services by the physician (or other billing practitioner) that are currently bundled, and increase payment rates for face-to-face prolonged E/M services by the physician (or other billing practitioner) based on existing RUC recommended values.

We are aware that CPT has approved a code to describe assessment and care planning for patients with cognitive impairment; however, it will not be ready in time for valuation in CY 2017. Therefore, we are proposing to make payment using a G-code (GPPP6—see below) for this service in 2017. We are also aware that CPT has approved three codes that describe services furnished consistent with the psychiatric CoCM, but that they will also not be ready in time for valuation in CY 2017. We discuss these services in more detail in the next section of this proposed rule. To facilitate separate payment for these services furnished to Medicare beneficiaries during CY 2017, we are proposing to make payment through the use of three G-codes (GPPP1, GPPP2, and GPPP3—see below) that parallel the new CPT codes, as well as a fourth G-code (GPPPX—see below) to describe services furnished using a broader application of behavioral health integration in the primary care setting. We intend for these to be temporary codes (for perhaps only one year) and will consider whether to adopt and establish values for the new CPT codes under our standard process, presumably for CY 2018. While we recognize that there may be overlap in the patient populations for the proposed new G-codes, we note that time spent by a practitioner or clinical staff cannot be counted more than once for any code (or assigned to more than one patient), consistent with PFS coding conventions.

Proposed payment for services described by new coding are as follows (please note that the descriptions included for GPPP1, GPPP2, and GPPP3 are from *Current Procedural Terminology* (CPT®) Copyright 2016 American Medical Association (and will be effective as part of CPT codes January 1, 2018). All rights reserved):

- GPPP1: Initial psychiatric collaborative care management, first 70 minutes in the first calendar month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional, with the following required elements:

++ Outreach to and engagement in treatment of a patient directed by the treating physician or other qualified health care professional;

++ Initial assessment of the patient, including administration of validated rating scales, with the development of an individualized treatment plan;

++ Review by the psychiatric consultant with modifications of the plan if recommended;

++ Entering patient in a registry and tracking patient follow-up and progress using the registry, with appropriate documentation, and participation in weekly caseload consultation with the psychiatric consultant; and

++ Provision of brief interventions using evidence-based techniques such as behavioral activation, motivational interviewing, and other focused treatment strategies.

- GPPP2: Subsequent psychiatric collaborative care management, first 60 minutes in a subsequent month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional, with the following required elements:

++ Tracking patient follow-up and progress using the registry, with appropriate documentation;

++ Participation in weekly caseload consultation with the psychiatric consultant;

++ Ongoing collaboration with and coordination of the patient's mental health care with the treating physician or other qualified health care professional and any other treating mental health providers;

++ Additional review of progress and recommendations for changes in treatment, as indicated, including medications, based on recommendations provided by the psychiatric consultant;

++ Provision of brief interventions using evidence-based techniques such as behavioral activation, motivational interviewing, and other focused treatment strategies;

++ Monitoring of patient outcomes using validated rating scales; and relapse prevention planning with patients as they achieve remission of symptoms and/or other treatment goals and are prepared for discharge from active treatment.

- GPPP3: Initial or subsequent psychiatric collaborative care management, each additional 30 minutes in a calendar month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional (List separately in addition to code for primary procedure) (Use GPPP3 in conjunction with GPPP1, GPPP2).
- GPPPX: Care management services for behavioral health conditions, at least 20 minutes of clinical staff time, directed by a physician or other qualified health care professional time, per calendar month.
- GPPP6: Cognition and functional assessment using standardized instruments with development of recorded care plan for the patient with cognitive impairment, history obtained from patient and/or caregiver, by the physician or other qualified health care professional in office or other outpatient setting or home or domiciliary or rest home.
- GPPP7: Comprehensive assessment of and care planning by the physician or other qualified health care professional for patients requiring chronic care management services, including assessment during the provision of a face-to-face service (billed separately from monthly care management services) (Add-on code, list separately in addition to primary service).
- GDDD1: Resource-intensive services for patients for whom the use of specialized mobility-assistive technology (such as adjustable height chairs or tables, patient lifts, and adjustable padded leg supports) is medically necessary and used during the provision of an office/outpatient evaluation and management visit (Add-on code, list separately in addition to primary procedure).

Additionally, we are aware that other codes are being developed through the CPT process. We have noted with interest that the CPT Editorial Panel and AMA/RUC restructured the former Chronic Care Coordination Workgroup to establish a new Emerging CPT and RUC Issues Workgroup that we hope will continue to consider the issues raised in this section of our CY 2017 proposed rule. We are continuing to consider possible additional codes for CCM services that would describe the time of the physician or other billing practitioner. We also remain interested in whether there should be changes under the PFS to reflect additional models of inter-professional collaboration for health conditions, in addition to those we are proposing for behavioral health integration.

For additional details on the coding and proposed valuation related to these proposals, see section II.L of this proposed rule for Valuation of Specific Codes. We note that the development of coding for these and other kinds of services across the PFS is typically an iterative process that responds to changes in medical practice and may be best refined over several years, with PFS rulemaking and the development of CPT codes as important parts of that process. Thus, we anticipate continuing the multi-year process of implementing initiatives designed to improve payment for, and recognize long-term investment in, primary care, care management and cognitive services, and patient-centered services.

2. Non-Face-To-Face Prolonged Evaluation & Management (E/M) Services

In public comments to the CY 2016 PFS proposed rule, many commenters recommended that CMS should establish separate payment for non-face-to-face prolonged E/M service codes that we currently consider to be "bundled" under the PFS (CPT codes 99358, 99359). The CPT descriptors are:

- CPT code 99358 (Prolonged evaluation and management service before and/or after direct patient care, first hour); and
- CPT code 99359 (Prolonged evaluation and management service before and/or after direct patient care, each additional 30 minutes (List separately in addition to code for prolonged service).

Commenters believed that separate payment for these existing CPT codes would provide a means for physicians and other billing practitioners to receive payment that more appropriately accounts for time that they spend providing non-face-to-face care. We agree that these codes would provide a means to recognize the additional resource costs of physicians and other practitioners when they spend an extraordinary amount of time outside the in-person office visit caring for the individual needs of their patients. And we believe that doing so in the context of the ongoing changes in health care practice to meet the current population's health care needs would be beneficial for Medicare beneficiaries and consistent with our overarching goals related to patient-centered care.

These non-face-to-face prolonged service codes are broadly described (although they include only time spent personally by the physician or other billing practitioner) and have a relatively high time threshold (the time counted must be beyond the usual service time for the primary or companion E/M code that is also billed). We believe this makes them sufficiently distinct from the other codes we propose to pay in CY 2017 as part of our primary care/care management/cognitive care initiative described in this section of our proposed rule. Accordingly, beginning in CY 2017 we propose to recognize CPT codes 99358 and 99359 for separate payment under the PFS. We note that time could not be counted more than once towards the provision of CPT codes 99358 or 99359 and any other PFS service. See section II.L for a discussion of our proposed valuation of CPT codes 99358 and 99359.

We propose to require the services to be furnished on the same day by the same physician or other billing practitioner as the companion E/M code. However, in reviewing the CPT guidance for CPT codes 99358 and 99359, we noted that CPT codes 99358 and 99359 should not be reported during the same service period as complex CCM services (CPT codes 99487, 99489) or TCM services (CPT codes 99495, 99496). One reason for excluding TCM and complex CCM services from concurrent billing would be that, like prolonged services, TCM and complex CCM services include substantial non-face-to-face work by the billing physician or other practitioner (an E/M visit and/or medical decision-making of moderate or high complexity). However, the CPT prolonged service with patient contact codes are billable on the same day an E/M service is furnished, and the CPT prolonged service codes without direct patient contact are services furnished during a single day that are directly related to a discrete face-to-face service. In contrast, TCM and CCM codes are billed monthly and focused on a broader episode of patient care. We are seeking public input on the intersection of the prolonged service codes with CCM and TCM services. We are also seeking public comment on the potential intersection of the prolonged service CPT codes 99358 and 99359 with proposed code GPPP7 (Comprehensive assessment of and care planning for patients requiring CCM services). Specifically, we are seeking comment regarding how distinctions among these services can be clearly delineated, including how the prolonged time can be clearly distinguished from typical pre- and post-service time, which is continued to be bundled with other codes. For all of these services, we have concerns that there may potentially be program integrity risks as the same non-face-to-face activities could be undertaken to meet the billing requirements for any of the above. We are seeking public comment to help us identify the full extent of program integrity considerations, as well as options for mitigating program integrity risks associated with these and other potentially overlapping codes.

3. Establishing Separate Payment for Behavioral Health Integration (BHI)

a. Psychiatric Collaborative Care Model (CoCM)

In the CY 2016 PFS final rule with comment period (80 FR 70920), we stated that we believed the care and management for Medicare beneficiaries with behavioral health conditions may include extensive discussion, information sharing and planning between a primary care physician and a specialist. We refer to this practice broadly as ''Behavioral Health Integration'' (BHI). In CY 2016 rulemaking, we described that in recent years, many randomized controlled trials have established an evidence base for an approach to caring for patients with behavioral health conditions called the psychiatric Collaborative Care Model (CoCM). A specific model for BHI, CoCM typically is provided by a primary care team, consisting of a primary care provider and a care manager who works in collaboration with a psychiatric consultant, such as a psychiatrist. Care is directed by the primary care team and includes structured care management with regular assessments of clinical status using validated tools and modification of treatment as appropriate. The psychiatric consultant provides regular consultations to the primary care team to review the clinical status and care of patients and to make recommendations. As we previously noted, several resources have been published that describe the psychiatric CoCM in greater detail and assess the impact of the model, including pieces from the University of Washington (*http://aims.uw.edu/*), the Institute for Clinical and Economic Review (*http://icer-review.org/announcements/icer-report-presents-evidence-based-guidance-to-support-integration-of-behavioral-health-into-primary-care/*), and the Cochrane Collaboration (*http://www.cochrane.org/CD006525/DEPRESSN_collaborative-care-forpeople-with-depression-and-anxiety*). Because this particular kind of collaborative care model has been tested and documented in medical literature, we expressed that we were particularly interested in comments on how coding under the PFS might facilitate appropriate valuation of the services furnished under the model. We also solicited comments to assist us in considering refinements to coding and payment to address this model in particular relative to current coding and payment policies, as well as information related to various requirements and aspects of these services.

After consideration of the comments, we are proposing to begin making separate payment for services furnished using the psychiatric CoCM beginning January 1, 2017. We are aware that CPT, recognizing the need for new coding for services under this model of care, has approved three codes to describe psychiatric collaborative care that is consistent with this model, but the codes will not be ready in time for valuation in CY 2017. Current CPT coding does not accurately describe or facilitate appropriate payment for the treatment of Medicare beneficiaries under this model of care. For example, under current Medicare payment policy, there is no payment made specifically for regular monitoring of patients using validated clinical rating scales or for regular psychiatric caseload review and consultation that does not involve face-to-face contact with the patient. We believe that these resources are directly involved in furnishing ongoing care management services to specific patients with specific needs, but they are not appropriately recognized under current coding and payment mechanisms. Because PFS valuation is based on the relative resource costs of the PFS services furnished to Medicare beneficiaries, we believe that appropriate coding for these services for CY 2017 will facilitate accurate payment for these and other PFS services. Therefore, we are proposing separate payment for services under the psychiatric CoCM using three new G-codes, as detailed above: GPPP1, GPPP2, and GPPP3, which would parallel the CPT codes that are being created to report these services. We intend for these to be temporary codes (for perhaps only one year) and will consider whether to adopt and establish values for the new CPT codes under our standard process, presumably for CY 2018.

Services in the psychiatric CoCM are provided under the direction of a treating physician or other qualified health care professional during a calendar month. These services are provided when a patient has a diagnosed psychiatric disorder that requires a behavioral health care assessment; establishing, implementing, revising, or monitoring a care plan; and provision of brief interventions. The diagnosis may be either pre-existing or made by the billing practitioner. These services are reported by the treating physician or other qualified health care professional and include the services of the treating physician or other qualified health care professional, the behavioral health care manager (see description below) who furnishes services incident to services of the treating physician or other qualified health care professional, and the psychiatric consultant (see description below) whose consultative services are furnished incident to services of the treating physician or other qualified health care professional. Patients who are appropriate candidates to participate in the psychiatric CoCM may have newly diagnosed conditions, need help in engaging in treatment, have not responded to standard care delivered in a non-psychiatric setting, or require further assessment and engagement prior to consideration of referral to a psychiatric care setting. Patients are treated under this model for an episode of care, defined as beginning when the behavioral health care manager engages in care of the patient under the appropriate supervision of the treating physician and ending with:

- The attainment of targeted treatment goals, which typically results in the discontinuation of care management services and continuation of usual follow-up with the treating physician or other qualified healthcare professional; or
- Failure to attain targeted treatment goals culminating in referral to a psychiatric care provider for ongoing treatment; or
- Lack of continued engagement with no psychiatric collaborative care management services provided over a consecutive six month calendar period (break in episode).

A new episode of care starts after a break in episode of six calendar months or more.

The treating physician or other qualified health care professional directs the behavioral health care manager and continues to oversee the patient's care, including prescribing medications, providing treatments for medical conditions, and making referrals to specialty care when needed. Medically necessary E/M and other services may be reported separately by the treating physician or other qualified health care professional, or other physicians or practitioners, during the same calendar month. Time spent by the treating physician or other qualified health care professional on activities for services reported separately may not be included in the services reported using GPPP1, GPPP2, and GPPP3. The behavioral health care manager under this model of care is a member of the treating physician or other qualified health care professional's clinical staff with formal education or specialized training in behavioral health (which could include a range of disciplines, for example, social work, nursing, and psychology) who provides care management services, as well as an assessment of needs, including the administration of validated rating scales,[2] the development of a care plan, provision of brief interventions, ongoing collaboration with the treating physician or other qualified health care professional, maintenance of a registry,[3] all in consultation with a psychiatric consultant. The behavioral health care manager furnishes these services both face-to-face and non-face-to-face, and consults with the psychiatric consultant minimally on a weekly basis. We would expect that the behavioral health care manager would be on-site at the location where the treating physician or other qualified health care professional furnishes services to the beneficiary.

The behavioral health care manager may or may not be a professional who meets all the requirements to independently furnish and report services to Medicare. If otherwise eligible, then that individual may report separate services furnished a beneficiary receiving the services described by GPPP1, GPPP2, GPPP3, and GPPPX in the same calendar month. These could include: psychiatric evaluation (90791, 90792), psychotherapy (90832, 90833, 90834, 90836, 90837, 90838), psychotherapy for crisis (90839, 90840), family psychotherapy (90846, 90847), multiple family group psychotherapy (90849), group psychotherapy (90853), smoking and tobacco use cessation counseling (99406, 90407), and alcohol or substance abuse structured screening and brief intervention services (99408, 99409). Time spent by the behavioral health care manager on activities for services reported separately may not be included in the services reported using time applied to GPPP1, GPPP2, and GPPP3.

The psychiatric consultant involved in the "incident to" care furnished under this model is a medical professional trained in psychiatry and qualified to prescribe the full range of medications. The psychiatric consultant advises and makes recommendations, as needed, for psychiatric and other medical care, including psychiatric and other medical diagnoses, treatment strategies including appropriate therapies, medication management, medical management of complications associated with treatment of psychiatric disorders, and referral for specialty services, that are communicated to the treating physician or other qualified health care professional, typically through the behavioral health care manager. The psychiatric consultant does not typically see the patient or prescribe medications, except in rare circumstances, but can and should facilitate a referral to a psychiatric care provider when clinically indicated.

In the event that the psychiatric consultant furnishes services to the beneficiary directly in the calendar month described by other codes, such as E/M services or psychiatric evaluation (90791, 90792), the services may be reported separately by the psychiatric consultant. Time spent by the psychiatric consultant on activities for services reported separately may not be included in the services reported using GPPP1, GPPP2, and GPPP3.

We also note that, although the psychiatric CoCM has been studied extensively in the setting of specific behavioral health conditions (for example, depression), we received persuasive comments last year recommending that we not specify particular diagnoses required for use of the codes for several reasons, including that: there may be overlap in behavioral health conditions; there are concerns that there could be modification of diagnoses to fit within payment rules which could skew the accuracy of submitted diagnosis code data; and for many patients for whom specialty care is not available, or who choose for other reasons to remain in primary care, primary care treatment will be more effective if it is provided within a model of integrated care that includes care management and psychiatric consultation.

(1) General Behavioral Health Integration (BHI)

We recognize that the psychiatric CoCM is prescriptive and that much of its demonstrated success may be attributable to adherence to a set of elements and guidelines of care as described in the preceding paragraphs. Therefore, we are proposing the use of these codes to pay accurately for this specific model of care for the benefit of Medicare beneficiaries, given its wide-spread adoption and recognized effectiveness. However, we note that PFS coding, in general, does not dictate how physicians practice medicine and believe that it should, instead, reflect the practice of medicine. We also recognize that there are primary care practices that are incurring, or may incur, resource costs inherent to treatment of patients with similar conditions based on other models of BHI that may benefit beneficiaries with behavioral health conditions (see, for example, the approach described at *http://www.integration.samhsa.gov/integrated-care-models.*) These models of care include resource costs associated with care managers and consultants that are not accurately characterized by the descriptions in the preceding paragraphs. However, these costs are also not included as direct PE inputs in other PFS services, such as E/M codes. In its comment regarding the psychiatric CoCM, MedPAC noted its preference for beneficiary-centered treatment that would allow for flexibility in addressing patient needs, rather than approaches that are tied to a particular model of care. MedPAC also urged CMS not to make separate payment for each care management activity.

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[2] For example, see *https://aims.uw.edu/resource-library/measurement-based-treatment-target.*

[3] For example, see *https://aims.uw.edu/collaborative-care/implementation-guide/plan-clinical-practice-change/identify-population-based.*

Therefore, to recognize the resource costs associated with furnishing behavioral health care management services to Medicare beneficiaries under related but different models of care without paying for each activity separately, we are also proposing to make payment using a new G-code that describes care management for beneficiaries with diagnosed behavioral health conditions under a broader application of integration in the primary care setting. We believe that for this subset of Medicare beneficiaries, the resources associated with medically necessary care management services are not otherwise adequately reflected under the PFS. The proposed code is GPPPX (Care management services for behavioral health conditions, at least 20 minutes of clinical staff time, directed by a physician or other qualified health care professional time, per calendar month). We note that we expect this coding to be refined over time as we receive more information about other behavioral health care models being used and how they are implemented.

We are seeking stakeholder input on whether we should consider requiring a longer duration of time for this code or an add-on to the code that would allow, for example, additional 20 minute increments. In addition, while we recognize that services inherent to models of BHI provided under this code may range in resource costs, we hope that appropriate payment for these services will lead to appropriate use of BHI models of care, which, in turn, will inform further refinement of the valuation in the future. For additional information on proposed valuation of these codes, see section II.L of this proposed rule.

(2) Initiating Visit for Proposed BHI Codes (GPPP1, GPPP2, GPPP3, and GPPPX)

Similar to CCM services (see section II.E.4), we propose to require an initiating visit for the BHI codes (both the psychiatric CoCM model and the general BHI code), that would be billable separately from the services themselves. We propose that the same services that can serve as the initiating visit for CCM services (see section II.E.3 of this proposed rule) can serve as the initiating visit for the proposed BHI codes. The initiating visit would establish the beneficiary's relationship with the billing practitioner (most aspects of the BHI services would be furnished incident to the billing practitioner's professional services), ensure the billing treating physician or other qualified health care professional assesses the patient prior to initiating other care management processes, and provides an opportunity to obtain beneficiary consent (discussed below). We welcome public comment on the types of services that are appropriate for an initiating visit for the BHI codes, and within what timeframe the initiating visit should be conducted prior to furnishing BHI services.

(3) Beneficiary Consent

Commenters to the CY 2016 PFS proposed rule indicated that they did not believe a specific patient consent for BHI services is necessary and, in fact, that requiring special informed consent for these services may reduce access due to stigma associated with behavioral health conditions. Instead, the commenters recommended requiring a more general consent prior to initiating these services whereby the beneficiary gives the initiating physician or practitioner permission to consult with relevant specialists, which would include conferring with a psychiatric consultant. Accordingly, we propose to require a general beneficiary consent to consult with relevant specialists prior to initiating these services, recognizing that applicable rules continue to apply regarding privacy. The proposed general consent would encompass conferring with a psychiatric consultant when furnishing the psychiatric CoCM codes (GPPP1, GPPP2, and GPPP3) or the broader BHI code (GPPPX). Similar to the proposed beneficiary consent process for CCM services (see section II.E.4 of this proposed rule), we propose that the billing practitioner must document in the beneficiary's medical record that the beneficiary's consent was obtained to consult with relevant specialists including a psychiatric consultant, and that, as part of the consent, the beneficiary is informed that there is beneficiary cost-sharing, including potential deductible and coinsurance amounts, for both in-person and non-face-to-face services that are provided. We welcome stakeholder comments on this proposal.

We recognize that special informed consent can also be helpful in cases when a particular service is limited to being billed by a single practitioner for a particular beneficiary. We do not believe that there are circumstances where it would reasonable for multiple practitioners to be reporting these codes during the same month. However, we are not proposing a formal limit at this time. We are seeking comment on whether such a limitation would be beneficial or whether there are circumstances under which a beneficiary might reasonably receive BHI services from more than one practitioner during a given month.

In recent months, many stakeholders have advised that we should waive the applicable Part B coinsurance for services such as those included in our proposed BHI codes. However, we currently lack statutory authority to waive the coinsurance for services such as these.

4. Reducing Administrative Burden and Improving Payment Accuracy for Chronic Care Management (CCM) Services

Beginning in CY 2015, we implemented separate payment for chronic care management (CCM) services under CPT code 99490 (Chronic care management services, at least 20 minutes of clinical staff time directed by a physician or other qualified health professional, per calendar month, with the following required elements:

- Multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient;
- Chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline;
- Comprehensive care plan established, implemented, revised, or monitored.

We finalized a proposal to make separate payment for CCM services as one initiative in a series of initiatives designed to improve payment for, and encourage long-term investment in, care management services (79 FR 67715). In particular, we sought to address an issue raised to us by the physician community, which asserted that the care management included in many of the existing E/M services, such as office visits, does not adequately describe the typical non-face-to-face care management work required by certain categories of beneficiaries (78 FR 43337). We began to re-examine how Medicare should pay under the PFS for non-face-to-face care management services that were bundled into the PFS payment for face-to-face E/M visits, being included in the pre- and post-encounter work (78 FR 43337). In proposing separate payment for CCM, we acknowledged that, even though we had previously considered non-face-to-face care management services as bundled into the payment for face-to-face E/M visits, the E/M office/outpatient visit CPT codes may not reflect all the services and resources required to furnish comprehensive, coordinated care management for certain categories of beneficiaries. We stated that we believed that the resources required to furnish complex chronic care management services to beneficiaries with multiple (that is, two or more) chronic conditions were not adequately reflected in the existing E/M codes. Medical practice and patient complexity required physicians, other practitioners and their clinical staff to spend increasing amounts of time and effort managing the care of comorbid beneficiaries outside of face-to-face E/M visits, for example complex and multidisciplinary care modalities that involve regular physician development and/or revision of care plans; subsequent report of patient status; review of laboratory and other studies; communication with other health care professionals not employed in the same practice who are involved in the patient's care; integration of new information into the care plan; and/or adjustments of medical therapy.

Therefore, in the CY 2014 PFS final rule with comment period, we established a separate payment under the PFS for CPT code 99490 (78 FR 43341 through 43342). We sought to include a relatively broad eligible patient population within the code descriptor, established a moderate payment amount, and established bundled payment for concurrently new CPT codes that were reserved for beneficiaries requiring "complex" CCM services (base CPT code 99487 and its add-on code 99489) (79 FR 67716 through 67719). We stated that we would evaluate the services reported under CPT code 99490 to assess whether the service is targeted to the right population and whether the payment amount is appropriate (79 FR 67719). We remind stakeholders that CMS did not limit the eligible population to any particular list of chronic conditions other than the language in the CPT code descriptor. Accordingly, one or more of the chronic conditions being managed through CCM services could be chronic mental health or behavioral health conditions or chronic cognitive disorders, as long as the chronic conditions meet the eligibility language in the CPT code descriptor for CCM services and the billing practitioner meets all of Medicare's requirements to bill the code including comprehensive, patient-centered care planning for all health conditions (see Table 11).

In finalizing separate payment for CPT code 99490, we considered whether we should develop standards to ensure that physicians and other practitioners billing the service would have the capability to fully furnish the service (79 FR 67721). We sought to make certain that the new PFS code(s) would provide beneficiary access to appropriate care management services that are characteristic of advanced primary care, such as patient support for chronic diseases to achieve health goals; 24/7 patient access to care and health information; receipt of preventive care; patient, family and caregiver engagement; and timely coordination of care through electronic health information exchange. Accordingly, we established a set of scope of service elements and payment rules in addition to or in lieu of those established in CPT guidance (in the CPT code descriptor and CPT prefatory language), that the physician or nonphysician practitioner must satisfy to fully furnish CCM services and report CPT code 99490 (78 FR 74414 through 74427, 79 FR 67715 through 67730, and 80 FR 14854). We established requirements to furnish a preceding qualifying visit, obtain advance written beneficiary consent, use certified electronic health record (EHR) technology to furnish certain elements of the service, share the care plan and clinical summaries electronically, document specified activities, and other items summarized in Table 11. For the CCM service elements for which we required use of a certified EHR, the billing practitioner must use, at a minimum, technology meeting the edition(s) of certification criteria that is acceptable for purposes of the EHR Incentive Programs as of December 31st of the calendar year preceding each PFS payment year. (For the CY 2017 PFS payment year, this would mean technology meeting the 2014 edition of certification criteria). These elements and requirements for separately payable CCM services are extensive and generally exceed those required for payment of codes describing procedures, diagnostic tests, or other E/M services under the PFS. In addition, both CPT guidance and our rules specify that only a single practitioner who assumes the care management role for a given beneficiary can bill CPT code 99490 per service period (calendar month). Because the new CCM service closely overlapped with several Medicare demonstration models of advanced primary care (the Multi-Payer Advanced Primary Care Practice (MAPCP) demonstration and the Comprehensive Primary Care Initiative (CPCI)), we provided that practitioners participating in one of these two initiatives could not be paid for CCM services furnished to a beneficiary attributed by the initiative to their practice (79 FR 67729).

Given the non-face-to-face nature of CCM services, we also sought to ensure that beneficiaries would receive advance notice that Part B cost sharing applies since we currently have no legislative authority to "waive" cost sharing for this service. Also since only one practitioner can bill for CCM each service period, we believed the beneficiary notice requirement would help prevent duplicate payment to multiple practitioners.

Since the establishment of CPT code 99490 for separate payment of CCM services, in a number of forums and in public comments to the CY 2016 PFS final rule (80 FR 70921), many practitioners have stated that the service elements and billing requirements are burdensome, redundant and prevent them from being able to provide the services to beneficiaries who could benefit from them. Stakeholders have stated that CPT 99490 is underutilized because it is underpaid relative to the resources involved in furnishing the services, especially given the extensive Medicare rules for payment, and they have suggested a number of potential changes to our current payment rules. Stakeholders continue to believe that many of the CCM payment rules are duplicative of other statutory and regulatory provisions, and to recommend that we reduce the rules and expand CCM coding and payment to distinguish among different levels of patient complexity. We also note that section 103 of the MACRA requires CMS to assess and report to Congress (no later than December 31, 2017) on access to CCM services by underserved rural and racial and ethnic minority populations and to conduct an outreach/education campaign that is underway.

Our assessment of claims data for CY 2015 for CPT code 99490 suggests that

CCM services may indeed be underutilized considering the number of eligible Medicare beneficiaries. Our analysis of Medicare claims data indicates that for CY 2015, approximately 275,000 unique Medicare beneficiaries received the service an average of 3 times each, totaling $37 million in allowed charges. Since CPT code 99490 describes a minimum of 20 minutes of clinical staff time spent furnishing CCM services during a month and does not have a time limit, and since we currently do not separately pay the other codes in the CCM family of CPT codes (which would provide us with utilization data on the number of patients requiring longer service times during a billing period), we do not know how often patients required more than 20 minutes of CCM services per month. We also do not know their relative complexity, other than meeting the acuity criteria in the CPT code descriptor. We also have no way to know the relative complexity of the CCM services furnished to beneficiaries.

In light of this stakeholder feedback and our mandate under MACRA section 103 to encourage and report on access to CCM services, we are proposing several changes in the payment rules for CCM services. Our primary goal and statutory mandate is to pay as accurately as possible for services furnished to Medicare beneficiaries based on the relative resources required to furnish PFS services, including CCM services. In so doing, we also expect to facilitate beneficiaries' access to reasonable and necessary CCM services that improve health outcomes. First, for CY 2017 we are proposing to more appropriately recognize and pay for the other codes in the CPT family of CCM services (CPT codes 99487 and 99489 describing complex CCM), consistent with our general practice to price services according to their relative ranking within a given family of services. We direct the reader to section II.L of this proposed rule for a discussion of proposed valuation for base CPT code 99487 and its add-on CPT code 99489. The CPT code descriptors are:

- CPT code 99487—Complex chronic care management services, with the following required elements:

++ Multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient;

++ Chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline;

++ Establishment or substantial revision of a comprehensive care plan;

++ Moderate or high complexity medical decision making;

++ 60 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month.

- CPT code 99489—Each additional 30 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month (List separately in addition to code for primary procedure).

As CPT provides, less than 60 minutes of clinical staff time in the service period could not be reported separately, and similarly, less than 30 minutes in addition to the first 60 minutes of complex CCM in a service period could not be reported. We would require 60 minutes of services for reporting CPT code 99487 and 30 additional minutes for each unit of CPT code 99489.

We propose to adopt the CPT provision that CPT codes 99487, 99489, 99490 may only be reported once per service period (calendar month) and only by the single practitioner who assumes the care management role with a particular beneficiary for the service period. That is, a given beneficiary would be classified as eligible to receive either complex or non-complex CCM during a given service period (calendar month), not both, and only one professional claim could be submitted to the PFS for CCM for that service period by one practitioner.

Except for differences in the CPT code descriptors, we propose to require the same CCM service elements for CPT codes 99487, 99489 and 99490. In other words, all the requirements in Table 11 would apply whether the code being billed for the service period is CPT code 99487 (plus 99489 if applicable) or CPT code 99490. These three codes would differ in the amount of clinical staff service time provided; the complexity of medical decision-making as defined in the E/M guidelines (determined by the problems addressed by the reporting practitioner during the month); and the nature of care planning that was performed (establishment or substantial revision of the care plan for complex CCM versus establishment, implementation, revision or monitoring of the care plan for non-complex CCM). Billing practitioners could consider identifying beneficiaries who require complex CCM services using criteria suggested in CPT guidance (such as number of illnesses, number of medications or repeat admissions or emergency department visits) or the profile of typical patients in the CPT prefatory language, but these would not comprise Medicare conditions of eligibility for complex CCM.

We are proposing several changes to our current scope of service elements for CCM, and are proposing that the same scope of service elements, as amended, would apply to all codes used to report CCM services beginning in 2017 (*i.e.,* CPT codes 99487, 99489 and 99490). In particular, we are proposing changes in the requirements for the initiating visit, 24/7 access to care and continuity of care, format and sharing of the care plan and clinical summaries, beneficiary receipt of the care plan, beneficiary consent, and documentation. In Table 11, we summarize the current scope of service elements and payment rules for CCM and indicate whether we are proposing to retain, remove or revise each element.

a. Initiating Visit

As provided in the CY 2014 PFS final rule with comment period (78 FR 74425) and subregulatory guidance (available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Downloads/Payment_for_CCM_Services_FAQ.pdf*), CCM must be initiated by the billing practitioner during a "comprehensive" E/M visit, annual wellness visit (AWV) or initial preventive physical exam (IPPE). This face-to-face, initiating visit is not part of the CCM service and can be separately billed to the PFS, but is required before CCM services can be provided directly or under other arrangements. The billing practitioner must discuss CCM with the patient at this visit. While informed patient consent does not have to be obtained during this visit, the visit is an opportunity to obtain the required consent. The face-to-face visit included in transitional care management (TCM) services (CPT 99495 and 99496) qualifies as a "comprehensive" visit for CCM initiation. Levels 2 through 5 E/M visits (CPT 99212 through 99215) also qualify; CMS does not require the practice to initiate CCM during a level 4 or 5 E/M visit. However CPT codes that do not involve a face-to-face visit by the billing practitioner or are not separately payable by Medicare (such as CPT 99211, anticoagulant management, online services, telephone and other E/M services) do not qualify as initiating visits. If the practitioner furnishes a "comprehensive" E/M, AWV, or IPPE and does not discuss CCM with the patient at that visit, that visit cannot count as the initiating visit for CCM.

We continue to believe that we should require an initiating visit in advance of furnishing CCM services, separate from the services themselves, because a face-to-face visit establishes the beneficiary's relationship with the billing practitioner (most aspects of the CCM services are furnished incident to the billing practitioner's professional services). The initiating visit also ensures collection of comprehensive health information to inform the care plan. We continue to believe that the types of face-to-face services that qualify as an initiating visit for CCM are appropriate. We are not proposing to change the kinds of visits that can qualify as initiating CCM visits. However we are proposing to require the initiating visit only for new patients or patients not seen within one year instead of for all beneficiaries receiving CCM services. We believe this will allow practitioners with existing relationships with patients who have been seen relatively recently to initiate CCM services without furnishing a potentially unnecessary E/M visit. We are seeking public comment on whether a period of time shorter than one year would be more appropriate.

We are also proposing for CY 2017 to create a new add-on G-code that would improve payment for visits that qualify as initiating visits for CCM services. The code would be billable for beneficiaries who require extensive face-to-face assessment and care planning by the billing practitioner (as opposed to clinical staff), through an add-on code to the initiating visit, GPPP7 (Comprehensive assessment of and care planning by the physician or other qualified health care professional for patients requiring chronic care management services (billed separately from monthly care management services) (Add-on code, list separately in addition to primary service). We propose that when the billing practitioner initiating CCM personally performs extensive assessment and care planning outside of the usual effort described by the billed E/M code (or AWV or IPPE code), the practitioner could bill GPPP7 in addition to the E/M code for the initiating visit (or in addition to the AWV or IPPE), and in addition to the CCM CPT code 99490 (or proposed 99487 and 99489) if all requirements to bill for CCM services are also met. See section II.L for proposed valuation of GPPP7.

The code GPPP7 would account specifically for additional work of the billing practitioner in personally performing a face-to-face assessment of a beneficiary requiring CCM services, and personally performing CCM care planning (the care planning could be face-to-face and/or non-face-to-face) that is not already reflected in the initiating visit itself (nor in the monthly CCM service code). We believe GPPP7 might be particularly appropriate to bill when the initiating visit is a less complex visit (such as a level 2 or 3 E/M visit), although GPPP7 could be billed along with higher level visits if the billing practitioner's effort and time exceeded the usual effort described by the initiating visit code. It could also be appropriate to bill GPPP7 when the initiating visit addresses problems unrelated to CCM, and the billing practitioner does not consider the CCM-related work he or she performs in determining what level of initiating visit to bill. We believe that this proposal will more appropriately recognize the relative resource costs for the work of the billing practitioner in initiating CCM services, specifically for extensive work assessing the beneficiary and establishing the CCM care plan that is reasonable and necessary, and that is not accounted for in the billed initiating visit or in the unit of the CCM service itself that is billed for a given service period. In addition, we believe this proposal will help ensure that the billing practitioner personally performs and meaningfully contributes to the establishment of the CCM care plan when the patient's complexity warrants it.

Consistent with general coding guidance, the work that is reported under GPPP7 (including time) could not also be reported under or counted towards the reporting of any other billed code, including any of the monthly CCM services codes. The care plan that the practitioner must create in order to bill GPPP7 would be subject to the same requirements as the care plan included in the monthly CCM services, namely it must be an electronic patient-centered care plan based on a physical, mental, cognitive, psychosocial, functional and environmental (re)assessment and an inventory of resources and supports; a comprehensive care plan for all health issues. This would distinguish it from the more limited care plan included in the BHI codes GPPP1, GPPP2, GPPP3 or GPPPX which focus on behavioral health issues, or the care plan included in GPPP6 which focuses on cognitive status. We are seeking public input on potential overlap among these codes and further clinical input as to how the assessments and care planning that is included in them would differ.

Finally, although not part of our proposals for 2017, we have noted with interest a recent CPT coding proposal for a code that would potentially identify and separately pay for monthly CCM work that is personally performed by the billing physician or other practitioner. We will continue to follow any CPT developments in this area.

b. 24/7 Access to Care and Continuity of Care

We propose several revisions to the scope of service elements of 24/7 Access to care and Continuity of Care. We continue to believe these elements are important aspects of CCM services, but that it would be appropriate to improve alignment with CPT provisions and remove the requirement for the care plan to be available remotely to individuals providing CCM services after hours. Studies have shown that after-hours care is best implemented as part of a larger practice approach to access and continuity (see for example, the peer-review article available at *http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3475839/*). There is substantial local variation in how 24/7 access and continuity of care are achieved, depending on the contractual relationships among practitioners and providers in a particular geographic area and other factors. Care models include various contractual relationships between physician practices and after-hours clinics, urgent care centers and emergency departments; extended primary care office hours; physician call-sharing; telephone triage systems; and health information technology such as shared EHRs and systematic notification procedures (*http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3475839/*). Some or all of these may be used to provide access to urgent care on a 24/7 basis while maintaining information continuity between providers.

We recognize that some models of care require more significant investment in practice infrastructure than others, for example resources in staffing or health information technology. In addition, we believe there is room to reduce the administrative complexity of our current payment rules for CCM services to accommodate a range of potential care models. In re-examining what should be included in the CCM scope of service elements for 24/7 Access to Care and Continuity of Care, we believe the CPT language adequately and more appropriately describes the services that should, at a minimum, be included in these service elements. Therefore, we propose to adopt the CPT language for these two elements. For 24/7 Access to Care, the scope of service element would be to provide 24/7 access to physicians or other qualified health care professionals or clinical staff including providing patients/caregivers with a means to make contact with health care professionals in the practice to address urgent needs regardless of the time of day or day of week. We believe the CPT language more accurately reflects the potential role of clinical staff or call-sharing services in addressing after-hours care needs than our current language does. In addition, the 24/7 access would be for "urgent" needs rather than "urgent chronic care needs," because we believe after-hours services typically would and should address any urgent needs and not only those explicitly related to the beneficiary's chronic conditions.

We recognize that health information systems that include remote access to the care plan or the full EHR after hours, or a feedback loop that communicates back to the primary care physician and others involved in the beneficiary's care regarding after-hours care or advice provided, are extremely helpful (*http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3475839/#CR25*). They help ensure that the beneficiary receives necessary follow up, particularly if he or she is referred to the emergency department, and follow up after an emergency department visit is required under the CCM element of Management of Care Transitions. Accordingly, we continue to support and encourage the use of interoperable EHRs or remote access to the care plan in providing the CCM service elements of 24/7 Access to Care, Continuity of Care, and Management of Care Transitions. However, adoption of such technology would be optimal not only for CCM services, but also for a number of other PFS services and procedures (including various other care management services), and we have not required adoption of any certified or non-certified health information technology as a condition of payment for any other PFS service. We note that there are incentives under other Medicare programs to adopt such information technology, and are concerned that imposing EHR-related requirements at the service level as a condition of PFS payment could create disparities between these services and others under the fee schedule. Lastly, we recognize that not all after-hours care warrants follow-up or a feedback loop with the practitioner managing the beneficiary's care overall, and that under particular circumstances feedback loops can be achieved through oral, telephone or other less sophisticated communication methods. Therefore at this time, we propose to remove the requirement that the individuals providing CCM after hours must have access to the electronic care plan. This proposal reflects our understanding that flexibility in how practices can provide the requisite 24/7 access to care, as well as continuity of care and management of care transitions, for their CCM patients can facilitate appropriate access to these services for Medicare beneficiaries. This proposal is not intended to undermine the significance of standardized communication methods as part of effective care. Instead, we recognize that other CMS initiatives may be better mechanisms to incentivize increased interoperability of health information systems than conditions of payment assigned to particular services under the PFS. We also anticipate that improved accuracy of payment for care management services and reduced administrative burden associated with billing for them will contribute to practitioners' capacity to invest in the best tools for managing the care of Medicare beneficiaries.

For Continuity of Care, we currently require the ability to obtain successive routine appointments "with the practitioner or a designated member of the care team," while CPT only references successive routine appointments "with a designated member of the care team." We do not believe there is any practical difference between these two phrases and therefore are proposing to omit the words "practitioner or" from our requirement. The billing practitioner is a member of the CCM care team, so the CPT language already allows for successive routine appointments either with the billing practitioner or another appropriate member of the CCM care team.

c. Electronic Care Plan

Based on review of extensive public comment and stakeholder feedback, we have come to believe that we should not require individuals providing the beneficiary with the required 24/7 access to care for urgent needs to have access to the care plan as a condition of CCM payment. As discussed above, we believe that in general, provision of effective after-hours care of the beneficiary would require access to the care plan, if not the full EHR. However, we have heard from rural and other practices that remote access to the care plan is not always necessary or possible because urgent care needs after-hours are often referred to a practitioner or care team member who established the care plan or is familiar with the beneficiary. In some instances, the care plan does not need to be available in order to address urgent patient needs after business hours. In addition, we have not required the use of any certified or non-certified health information technology in the provision of any other PFS services (including various other care management services). We are concerned that imposing EHR-related requirements at the service level as a condition of PFS payment could distort the relative valuation of services priced under the fee schedule. Therefore, we propose to change the CCM service element to require timely electronic sharing of care plan information within and outside the billing practice, but not necessarily on a 24/7 basis, and to allow transmission of the care plan by fax.

We acknowledge that it is best for practitioners and providers to have access to care plan information any time they are providing services to beneficiaries who require CCM services. This proposal is not intended to undermine the significance of electronic communication methods other than fax transmission in providing effective, continuous care. On the contrary, we believe that fax transmission, while commonly used, is much less efficient and secure than other methods of communicating patient health information, and we encourage practitioners to adopt and use electronic technologies other than fax for transmission and exchange of the CCM care plan. We continue to believe the best means of exchange of all relevant patient health information is through standardized electronic means. However, we recognize that other CMS initiatives may be better mechanisms to incentivize increased interoperability of health information systems than conditions of payment assigned to particular services under the PFS. We believe our proposal would still allow timely availability of health information within and outside the practice for purposes of providing CCM, and would simplify the rules governing provision of the service and improve access to the service. These proposed revisions would better align the service with appropriate CPT prefatory language, which may reduce unnecessary administrative complexity for practitioners in navigating the differences between CPT guidance and Medicare rules.

d. Clinical Summaries

The CCM scope of service element Management of Care Transitions includes a requirement for the creation and electronic transmission and exchange of continuity of care documents referred to as "clinical summaries" (see Table 11). We patterned our requirements regarding clinical summaries after the EHR Incentive Program requirement that an eligible professional who transitions their patient to another setting of care or provider of care, or refers their patient to another provider of care, should provide a summary care record for each transition of care or referral. This clinical summary includes demographics, the medication list, medication allergy list, problem list, and a number of other data elements if the practitioner knows them. As a condition of CCM payment, we required standardized content for clinical summaries (that they must be created/formatted according to certified EHR technology). For the exchange/transport function, we did not require the use of a specific tool or service to exchange/transmit clinical summaries, as long as they are transmitted electronically (this can include fax only when the receiving practitioner or provider can only receive by fax).

Based on review of extensive public comment and stakeholder feedback, we have come to believe that we should not require the use of any specific electronic technology in managing a beneficiary's care transitions as a condition of payment for CCM services. Instead we are proposing more simply to require the billing practitioner to create and exchange/transmit continuity of care document(s) timely with other practitioners and providers. To avoid confusion with the requirements of the EHR Incentive Programs, and since we would no longer require standardized content for the CCM continuity of care document(s), we would refer to them as continuity of care documents instead of clinical summaries. We would no longer specify how the billing practitioner must transport or exchange these document(s), as long as it is done timely and consistent with the Care Transitions Management scope of service element. We welcome public input on how we should refer to these document(s), noting that CPT does not provide model language specific to CCM services. The proposed term "continuity of care document(s)" draws on CPT prefatory language for TCM services, which CPT provides may include "obtaining and reviewing the discharge information (for example, discharge summary, as available, or continuity of care document)."

Again, this proposal is not intended to undermine the significance of a standardized, electronic format and means of exchange (other than fax) of all relevant patient health information, for achieving timely, seamless care across settings especially after discharge from a facility. On the contrary, we believe that fax transmission, while commonly used, is much less efficient and secure than other methods of communicating patient health information, and we encourage practitioners to adopt and use electronic technologies other than fax for transmission and exchange of continuity of care documents in providing CCM services. We continue to believe the best means of exchange of all relevant patient health information is through standardized electronic means. However, as we discussed above regarding the CCM care plan, we have not applied similar requirements to other PFS services specifically (including various other care management services) and have concerns about how doing so may create disparities between these services and others under the PFS. We also recognize that other CMS initiatives may be better mechanisms to incentivize increased interoperability of health information systems than conditions of payment assigned to particular services under the PFS. However, we also anticipate that our proposals will contribute to practitioners' capacity to invest in the best tools for managing the care of Medicare beneficiaries.

e. Beneficiary Receipt of Care Plan

We propose to simplify the current requirement to provide the beneficiary with a written or electronic copy of the care plan, by instead adopting the CPT language specifying more simply that a copy of the care plan must be given to the patient or caregiver. While we believe beneficiaries should and must be provided a copy of the care plan, and that practitioners may choose to provide the care plan in hard copy or electronic form in accordance with patient preferences, we do not believe it is necessary to specify the format of the care plan that must be provided as a condition of CCM payment. Additionally, we recognize that there may be times that sharing the care plan with the caregiver (in a manner consistent with applicable privacy and security rules and regulations) may be appropriate.

f. Beneficiary Consent

We continue to believe that obtaining advance beneficiary consent to receive CCM services is important to ensure the beneficiary is informed, educated about CCM services, and is aware of applicable cost sharing. We also believe that querying the beneficiary about whether another practitioner is already providing CCM services helps to reduce the potential for duplicate provision or billing of the services. However, we believe the consent process could be simplified, and that it should be left to the practitioner and the beneficiary to decide the best way to establish consent. Therefore, we propose to continue to require billing practitioners to inform the beneficiary of the currently required information (that is, inform the beneficiary of the availability of CCM services; inform the beneficiary that only one practitioner can furnish and be paid for these services during a calendar month; and inform the beneficiary of the right to stop the CCM services at any time (effective at the end of the calendar month)). However, we propose to specify that the practitioner could document in the beneficiary's medical record that this information was explained and note whether the beneficiary accepted or declined CCM services instead of obtaining a written agreement.

We also propose to remove the language requiring beneficiary authorization for the electronic communication of his or her medical information with other treating providers as a condition of payment for CCM services, because under the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule (45 CFR 164.506), a covered entity is permitted to use or disclose protected health information for purposes of treatment without patient authorization. Moreover, if such disclosure is electronic, the HIPAA Security Rule requires secure transmission (45 CFR 164.312(e)). In previous regulations we have reminded practitioners that for all electronic sharing of beneficiary information in the provision of CCM services, HIPAA Privacy and Security Rule standards apply in the usual manner (79 FR 67728).

g. Documentation

We have heard from practitioners that the requirements to document certain information in a certified EHR format are redundant because the CCM billing rules already require documentation of core clinical information in a certified EHR format. Specifically, we already require structured recording of demographics, problems, medications and medication allergies, and the creation of a clinical summary record, using a qualifying certified EHR; and that a full list of problems, medications and medication allergies in the EHR must inform the care plan, care coordination and ongoing clinical care. Therefore, we propose to no longer require the use of a qualifying certified EHR to document communication to and from home- and community-based providers regarding the patient's psychosocial needs and functional deficits and to document beneficiary consent. We would continue to require documentation in the medical record of beneficiary consent (discussed above) and of communication to and from home- and community-based providers regarding the patient's psychosocial needs and functional deficits.

In summary, we believe our proposed changes would retain elements of the CCM service that are most characteristic of the changes in medical practice toward advanced primary care, while eliminating redundancy, simplifying provision of the services, and improving access without compromising quality of care and beneficiary privacy or advance notice and consent. We also anticipate that improved accuracy of payment for care management services and reduced administrative burden associated with billing for these services will contribute to practitioners' capacity to invest in the best tools for managing the care of Medicare beneficiaries.

g. CCM Requirements for Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)

RHCs and FQHCs have been authorized to bill for CCM services since January 1, 2016, and are paid based on the Medicare PFS national average non-facility payment rate when CPT code 99490 is billed alone or with other payable services on a RHC or FQHC claim. The RHC and FQHC requirements for billing CCM services have generally followed the requirements for practitioners billing under the PFS, with some adaptations based on the RHC and FQHC payment methodologies.

To assure that CCM requirements for RHCs and FQHCs are not more burdensome than those for practitioners billing under the PFS, we are proposing revisions for CCM services furnished by RHCs and FQHCs similar to the revisions proposed under the section above entitled, "Reducing Administrative Burden and Improving Payment Accuracy for Chronic Care Management (CCM) Services" for RHCs and FQHCs. Specifically, we propose to:

- Require that CCM be initiated during an AWV, IPPE, or comprehensive E/M visit only for new patients or patients not seen within one year. This would replace the requirement that CCM could only be initiated during an AWV, IPPE, or comprehensive E/M visit where CCM services were discussed.
- Require 24/7 access to a RHC or FQHC practitioner or auxiliary staff with a means to make contact with a RHC or FQHC practitioner to address urgent health care needs regardless of the time of day or day of week. This would replace the requirement that CCM services be available 24/7 with health care practitioners in the RHC or FQHC who have access to the patient's electronic care plan to address his or her urgent chronic care needs, regardless of the time of day or day of the week.
- Require timely electronic sharing of care plan information within and outside the RHC or FQHC, but not necessarily on a 24/7 basis, and allow transmission of the care plan by fax. This would replace the requirement that the electronic care plan be available on a 24/7 basis to all practitioners within the RHC or FQHC whose time counts towards the time requirement for the practice to bill the CCM code, and removes the restriction on allowing the care plan to be faxed.
- Require that in managing care transitions, the RHC or FQHC creates, exchanges, and transmits continuity of care document(s) in a timely manner with other practitioners and providers. This would replace the requirements that clinical summaries must be created and formatted according to certified EHR technology, and the requirement for electronic exchange of clinical summaries by a means other than fax.
- Require that a copy of the care plan be given to the patient or caregiver. This would remove the description of the format (written or electronic) and allows the care plan to be provided to the caregiver when appropriate (and in a manner consistent with applicable privacy and security rules and regulations).
- Require that the RHC or FQHC practitioner documents in the beneficiary's medical record that all the elements of beneficiary consent (for example, that the beneficiary was informed of the availability of CCM services; only one practitioner can furnish and be paid for these services during a calendar month; the beneficiary may stop the CCM services at any time, effective at the end of the calendar month, etc.) were provided, and whether the beneficiary accepted or declined CCM services. This would replace the requirement that RHCs and FQHCs obtain a written agreement that these elements were discussed, and removes the requirement that the beneficiary provide authorization for the electronic communication of his or her medical information with other treating providers as a condition of payment for CCM services.
- Require that communication to and from home- and community-based providers regarding the patient's psychosocial needs and functional deficits be documented in the patient's medical record. This would replace the requirement to document this patient health information in a certified EHR format.

We note that we are not proposing an additional payment adjustment for patients who require extensive assessment and care planning as part of the initiating visit, as payments for RHC and FQHC services are not adjusted for length or complexity of the visit.

We believe these proposed changes would keep the CCM requirements for RHCs and FQHCs consistent with the CCM requirements for practitioners billing under the PFS, simplify the provision of CCM services by RHCs and FQHCs, and improve access to these services without compromising quality of care, beneficiary privacy, or advance notice and consent.

TABLE 11—CHRONIC CARE MANAGEMENT (CCM) SCOPE OF SERVICE ELEMENTS AND BILLING REQUIREMENTS

CCM Scope of service element/billing requirement	Propose to retain	Propose to remove	Proposed revision
Initiating Visit—Initiation during an AWV, IPPE, or face-to-face E/M visit for all patients (Level 4 or 5 visit not required).	....	....	Initiation during an AWV, IPPE, or face-to-face E/M visit (Level 4 or 5 visit not required) for new patients or patients not seen within 1 year.
Structured Recording of Patient Information Using Certified EHR Technology—Structured recording of demographics, problems, medications, medication allergies, and the creation of a structured clinical summary record, using certified EHR technology. A full list of problems, medications and medication allergies in the EHR must inform the care plan, care coordination and ongoing clinical care.	....	....	*Structured Recording of Patient Information Using Certified EHR Technology*—Structured recording of demographics, problems, medications and medication allergies using certified EHR technology. A full list of problems, medications and medication allergies in the EHR must inform the care plan, care coordination and ongoing clinical care.

TABLE 11—CHRONIC CARE MANAGEMENT (CCM) SCOPE OF SERVICE ELEMENTS AND BILLING REQUIREMENTS—Continued

CCM Scope of service element/billing requirement	Propose to retain	Propose to remove	Proposed revision
24/7 Access to Care—Access to care management services 24/7 (providing the beneficiary with a means to make timely contact with health care practitioners in the practice who have access to the patient's electronic care plan to address his or her urgent chronic care needs regardless of the time of day or day of the week).	....	....	Provide 24/7 access to physicians or other qualified health professionals or clinical staff including providing patients/caregivers with a means to make contact with health care professionals in the practice to address urgent needs regardless of the time of day or day of week.
Continuity of Care—Continuity of care with a designated practitioner or member of the care team with whom the beneficiary is able to get successive routine appointments.	....	....	Continuity of care with a designated member of the care team with whom the beneficiary is able to schedule successive routine appointments.
Comprehensive Care Management—Care management for chronic conditions including systematic assessment of the beneficiary's medical, functional, and psychosocial needs; system-based approaches to ensure timely receipt of all recommended preventive care services; medication reconciliation with review of adherence and potential interactions; and oversight of beneficiary self-management of medications.	X	....	
Electronic Comprehensive Care Plan—Creation of an electronic patient-centered care plan based on a physical, mental, cognitive, psychosocial, functional and environmental (re)assessment and an inventory of resources and supports; a comprehensive care plan for all health issues.	X	....	
Electronic Sharing of Care Plan—Must at least electronically capture care plan information; make this information available on a 24/7 basis to all practitioners within the practice whose time counts towards the time requirement for the practice to bill the CCM code; and share care plan information electronically (by fax in extenuating circumstance) as appropriate with other practitioners and providers.	....	....	Must at least electronically capture care plan information, and make this information available timely within and outside the billing practice as appropriate. Share care plan information electronically (can include fax) and timely within and outside the billing practice to individuals involved in the beneficiary's care.
Beneficiary Receipt of Care Plan—Provide the beneficiary with a written or electronic copy of the care plan.	....	....	A copy of the plan of care must be given to the patient or caregiver.
Documentation of care plan provision to beneficiary—Document provision of the care plan as required to the beneficiary using certified EHR technology.	....	X	
Management of Care Transitions .... • Management of care transitions between and among health care providers and settings, including referrals to other clinicians; follow-up after an emergency department visit; and follow-up after discharges from hospitals, skilled nursing facilities or other health care facilities. • Format clinical summaries according to certified EHR technology (content standard). • Not required to use a specific tool or service to exchange/transmit clinical summaries, as long as they are transmitted electronically (by fax in extenuating circumstance).	....	....	*Management of Care Transitions* • Management of care transitions between and among health care providers and settings, including referrals to other clinicians; follow-up after an emergency department visit; and follow-up after discharges from hospitals, skilled nursing facilities or other health care facilities. • Create and exchange/transmit continuity of care document(s) timely with other practitioners and providers.
Home- and Community-Based Care Coordination—Coordination with home and community based clinical service providers.	X	....	
Documentation of Home- and Community-Based Care Coordination—Communication to and from home- and community-based providers regarding the patient's psychosocial needs and functional deficits must be documented in the patient's medical record using certified EHR technology.	....	....	Communication to and from home- and community-based providers regarding the patient's psychosocial needs and functional deficits must be documented in the patient's medical record.

TABLE 11—CHRONIC CARE MANAGEMENT (CCM) SCOPE OF SERVICE ELEMENTS AND BILLING REQUIREMENTS—Continued

CCM Scope of service element/billing requirement	Propose to retain	Propose to remove	Proposed revision
Enhanced Communication Opportunities—Enhanced opportunities for the beneficiary and any caregiver to communicate with the practitioner regarding the beneficiary's care through not only telephone access, but also through the use of secure messaging, Internet, or other asynchronous non-face-to-face consultation methods.	X	....	
Beneficiary Consent— • Inform the beneficiary of the availability of CCM services and obtain his or her written agreement to have the services provided, including authorization for the electronic communication of his or her medical information with other treating providers. • Inform the beneficiary of the right to stop the CCM services at any time (effective at the end of the calendar month) and the effect of a revocation of the agreement on CCM services. • Inform the beneficiary that only one practitioner can furnish and be paid for these services during a calendar month. • Document the beneficiary's written consent and authorization using certified EHR technology.	....	....	• Inform the beneficiary of the availability of CCM services. • Inform the beneficiary that only one practitioner can furnish and be paid for these services during a calendar month. • Inform the beneficiary of the right to stop the CCM services at any time (effective at the end of the calendar month). • Document in the beneficiary's medical record that the required information was explained and whether the beneficiary accepted or declined the services.

5. Assessment and Care Planning for Patients With Cognitive Impairment

For CY 2017 we are proposing a G-code that would provide separate payment to recognize the work of a physician (or other appropriate billing practitioner) in assessing and creating a care plan for beneficiaries with cognitive impairment, GPPP6 (Cognition and functional assessment using standardized instruments with development of recorded care plan for the patient with cognitive impairment, history obtained from patient and/or caregiver, in office or other outpatient setting or home or domiciliary or rest home). We understand that a similar code was recently approved by the CPT Editorial Panel and is scheduled to be included in the CY 2018 CPT code set. We intend for GPPP6 to be a temporary code (perhaps for only one-year) and will consider whether to adopt and establish relative value units for the new CPT code under our standard process, presumably for CY 2018.

We reviewed the list of service elements that were proposed at CPT, and are proposing the following as required service elements of GPPP6:

- Cognition-focused evaluation including a pertinent history and examination.
- Medical decision making of moderate or high complexity (defined by the E/M guidelines).
- Functional assessment (for example, Basic and Instrumental Activities of Daily Living), including decision-making capacity.
- Use of standardized instruments to stage dementia.
- Medication reconciliation and review for high-risk medications, if applicable.
- Evaluation for neuropsychiatric and behavioral symptoms, including depression, including use of standardized instrument(s).
- Evaluation of safety (for example, home), including motor vehicle operation, if applicable.
- Identification of caregiver(s), caregiver knowledge, caregiver needs, social supports, and the willingness of caregiver to take on caregiving tasks.
- Advance care planning and addressing palliative care needs, if applicable and consistent with beneficiary preference.
- Creation of a care plan, including initial plans to address any neuropsychiatric symptoms and referral to community resources as needed (for example, adult day programs, support groups); care plan shared with the patient and/or caregiver with initial education and support.

The proposed valuation of GPPP6 (discussed in section II.E.1) assumes that this code would include services that are personally performed by the physician (or other appropriate billing practitioner) and would significantly overlap with services described by certain E/M visit codes, advance care planning services, and certain psychological or psychiatric service codes that are currently separately payable under the PFS. Accordingly, we propose that GPPP6 must be furnished by the physician (or other appropriate billing practitioner) and could not be billed on the same date of service as CPT codes 90785 (Psytx complex interactive), 90791 (Psych diagnostic evaluation), 90792 (Psych diag eval w/ med srvcs), 96103 (Psycho testing admin by comp), 96120 (Neuropsych tst admin w/comp), 96127 (Brief emotional/behav assmt), 99201–99215 (Office/outpatient visits new), 99324–99337 (Domicil/r-home visits new pat), 99341–99350 (Home visits new patient), 99366–99368 (Team conf w/pat by hc prof), 99497 (Advncd care plan 30 min), 99498 (Advncd care plan addl 30 min)), since these codes all reflect face-to-face services provided by the physician or other billing practitioner for related services that are separately payable. In addition, we are proposing to prohibit billing of GPPP6 with other care planning services, such as care plan oversight services (CPT code 99374), home health care and hospice supervision (G0181, G0182), or our proposed add-on code for comprehensive assessment and care planning by the billing practitioner for patients requiring CCM services (GPPP7). We are seeking comment on whether there are circumstances where multiple care planning codes could be furnished without significant overlap. We propose to specify that GPPP6 may serve as a companion or primary E/M code to the prolonged service codes (those that are currently separately paid, and those we propose to separately pay beginning in 2017), but are interested in public input on whether there is any overlap among these services. We are seeking comment on how to best delineate the post-service work for GPPP6 from the work necessary to provide the prolonged services code.

We do not believe the services described by GPPP6 would significantly overlap with proposed or current medically necessary CCM services (CPT codes 99487, 99489, 99490); TCM services (99495, 99496); or the proposed behavioral health integration service codes (GPPP1, GPPP2, GPPP3, GPPPX). Therefore we propose that GPPP6 could be billed on the same date-of-service or within the same service period as these codes (CPT codes 99487, 99489, 99490, 99495, 99496, GPPP1, GPPP2, GPPP3, GPPPX). There may be overlap in the patient population eligible to receive these services and the population eligible to receive the services described by GPPP6, but we believe there would be sufficient differences in the nature and extent of the assessments, interventions and care planning, as well as the qualifications of individuals providing the services, to allow concurrent billing for services that are medically reasonable and necessary. We welcome public comment on potential overlap between GPPP6 and existing PFS billing codes, as well as the other primary care/cognitive services addressed in this section of the proposed rule.

6. Improving Payment Accuracy for Care of People With Disabilities

a. Background

People with disabilities face significant challenges accessing the health care system. Medicare beneficiaries who are under age 65 with disabilities are three times more likely to report having difficulties finding a doctor who accepts Medicare than beneficiaries age 65 and older.[4] When able to find a Medicare participating physician, people with disabilities report worse experiences than people without disabilities on many quality measures, including those related to patient-centered care and patient safety based on data from the National Healthcare Disparities Report, produced by the Agency for Healthcare Research and Quality (AHRQ).[5] The reasons for these access and quality disparities are multifaceted and may include a range of payment challenges, accessibility issues with equipment and facilities, communication obstacles, and sometimes lack of practitioner understanding of how to assess and fully address the needs and preferences of people with disabilities. The Equity Plan for Improving Quality in Medicare, released last fall by CMS, highlights many challenges in achieving better outcomes for people with disabilities.

One way to help improve access to high-quality physicians' services for people with disabilities is to ensure Medicare Physician Fee Schedule payments are based on the accurate relative resource costs of services furnished to people with disabilities.

As described in section I.B. of this proposed rule, PFS payments are required to be based on the relative resources involved in furnishing a service. To determine the relative resources required to furnish a service described by a specific HCPCS code, CMS considers the "typical" Medicare service described by that code, and identifies the resources involved in that scenario. This approach assumes that while practitioners might incur greater or fewer costs in furnishing any specific service to any particular beneficiary, RVUs are allocated appropriately based on a "typical" Medicare case-mix.

For HCPCS codes that describe narrowly-defined procedures and tests, PFS payment rates based on the typical resources may be accurate for most kinds of practitioners and many beneficiaries, because the granularity of coding corresponds with practitioners' use of resources based on the specific medical needs of their patients. However, the HCPCS codes that describe the office/outpatient E/M services are broadly defined, so the typical service billed using one of those HCPCS codes matches a much smaller percentage of all the services billed using that HCPCS code. Medicare payment rates for these kinds of services under the PFS do not vary by the population being served, or by the particular practitioner furnishing the services. Payment for these kinds of service vary only based on the delineations among the level of visits, despite the reality that adequately serving certain patients requires much greater resources in ways that are generally not reflected in the described differentiation between visit levels.

For example, the same codes and rates are used to pay for routine care of all patients, including furnishing care to patients with disabilities that often require greater resources relating to equipment, clinical staff, and physician time relative to the resource costs associated with providing the same kind of care to other Medicare beneficiaries. Thus, the payment rate for the code may not accurately reflect the resources involved in providing the service to certain categories of beneficiaries. For these reasons, the resources involved in furnishing care, including and especially routine care of both acute and chronic illness, to beneficiaries with disabilities may be routinely and systematically underestimated under PFS payment made on the basis of the broadly described visit codes. This effectively reduces overall payment relative to resource needs for practitioners who more frequently serve such patients, which could negatively impact access or quality of care for beneficiaries with disabilities.

b. Establishing a HCPCS G-Code To Improve Payment Accuracy for Care of People With Mobility-Related Disabilities

We estimate that about 7 percent of all Medicare beneficiaries have a potentially disabling mobility-related diagnosis (the Medicare-only prevalence is 5.5 percent and the prevalence for Medicare-Medicaid dual eligible beneficiaries is 11 percent), using 2010 Medicare (and for dual eligible beneficiaries, Medicaid) claims data.

When a beneficiary with a mobility-related disability goes to a physician or other practitioner's office for an E/M visit, the resources associated with providing the visit can exceed the resources required for the typical E/M visit. An E/M visit for a patient with a mobility-related disability can require more physician and clinical staff time to provide appropriate care because the patient may require skilled assistance throughout the visit to carefully move and adjust his/her body. Furthermore, an E/M visit for a patient with a mobility-related disability commonly requires specialized equipment such as a wheel chair accessible scale, floor and overhead lifts, a movable exam table, padded leg supports, a stretcher and transfer board. The current E/M visit payment rates, based on an assumption of "typical" resources involved in furnishing an E/M visit to a "typical" patient, do not accurately reflect these additional resources associated with furnishing appropriate care to many beneficiaries with mobility-related disabilities.

When furnishing E/M services to beneficiaries with mobility-related disabilities, practitioners face difficult choices in deciding whether to take the extra time necessary and invest in the required specialized equipment for these visits even though the payment rate for the service does not account for either expense; potentially providing less than optimal care for a beneficiary whose needs exceed the standard appointment block of time in the standard equipped exam room reflected in the current E/M visit payment rate; or declining to accept appointments altogether for beneficiaries who require additional time and specialized equipment.

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[4] The Henry J Kaiser Family Foundation. 2010. "Medicare and Nonelderly People with Disabilities."

[5] National Healthcare Disparities Report, 2013. May 2014. Agency for Healthcare Research and Quality, Rockville, MD. The National Healthcare Disparities Report summarizes health care quality and access among various racial, ethnic, and income groups and other priority populations, such as residents of rural areas and people with disabilities.

Each of these scenarios is potentially problematic. The first two scenarios suggest that the quality of care for this beneficiary population might be compromised by assumptions under the PFS regarding relative resource costs in furnishing services to this population. The third scenario reflects an obvious access problem for these beneficiaries. To improve payment accuracy and help ameliorate potential disparity in access and quality for beneficiaries with mobility-related disabilities, we propose to create a new add-on G-code, effective for CY 2017, to describe the additional services furnished in conjunction with E/M services to beneficiaries with disabilities that impair their mobility:

- GDDD1: Resource-intensive services for patients for whom the use of specialized mobility-assistive technology (such as adjustable height chairs or tables, patient lifts, and adjustable padded leg supports) is medically necessary and used during the provision of an office/outpatient evaluation and management service visit (Add-on code, list separately in addition to primary procedure).

Effective January 1, 2017, we propose that this add-on code could be billed with new and established patient office/outpatient E/M codes (CPT codes 99201 through 99205, and 99212 through 99215), as well as transitional care management codes (CPT codes 99495 and 99496), when the additional resources described by the code are medically necessary and used in the provision of care. In addition to seeking comment on this proposal, we are also seeking comment on other HCPCS codes that may be appropriate base codes for this proposed add-on code, including those describing preventive visits and services. We remind potential commenters that the rationale for this proposal is based in large part on the broad use and lack of granularity in coding for E/M services relative to other PFS services in conjunction with the additional resources used.

The proposed inputs and valuation for this code are detailed in section II.L of this proposed rule.

c. Soliciting Comment on Other Coding Changes To Improve Payment Accuracy for Care of People With Disabilities

When furnishing care to a beneficiary with a mobility-related disability, the current E/M visit payment rates may not fully reflect the associated resource costs that are being incurred by practitioners. We recognize that there are other populations for which payment adjustment may be appropriate. Our proposal regarding beneficiaries with mobility-related disabilities reflects the discrete nature of the additional resource costs for this population, the clear lack of differentiation in resource costs regarding particular kinds of frequently-furnished services, and the broad recognition of access problems. We recognize that some physician practices may frequently furnish services to particular populations for which the relative resource costs are similarly systemically undervalued and we seek comment regarding other circumstances where these dynamics can be discretely observed.

7. Supervision for Requirements for Non-Face-to-Face Care Management Services

Our current regulations in § 410.26(b) provide for an exception to allow general supervision of CCM services (and similarly, for the non-face-to-face portion of TCM services), because these are non-face-to-face care management/care coordination services that would commonly be provided by clinical staff when the billing practitioner, and hence, the supervising physician, is not physically present; and the CPT codes are comprised solely (or largely) of non-face-to-face services provided by clinical staff. A number of codes that we are proposing to establish for separate payment in CY 2017 under our initiative to improve payment accuracy for primary care and care management are similar to CCM services in that a critical element of the services is non-face-to-face care management/care coordination services provided by clinical staff when the billing practitioner may not be physically present. Accordingly, we are proposing to amend § 410.26(a)(3) and § 410.26 (b) to better define general supervision and to allow general supervision not only for CCM services and the non-face-to-face portion of TCM services, but also for proposed codes GPPP1, GPPP2, GPPP3, GPPPX, CPT code 99487, and CPT code 99489. Instead of adding each of these proposed codes requiring general supervision to the regulation text on an individual basis, we propose to revise our regulation under paragraph (b)(1) of § 410.26 to allow general supervision of the non-face-to-face portion of designated care management services, and we would designate the applicable services through notice and comment rulemaking.

F. Improving Payment Accuracy for Services: Diabetes Self-Management Training (DSMT)

Section 1861(s)(2)(S) of the Act specifies that medical and other health services include DSMT services as defined in section 1861(qq) of the Act. DSMT services are intended to educate beneficiaries in the successful self-management of diabetes. DSMT includes, as applicable, instructions in self-monitoring of blood glucose; education about diet and exercise; an insulin treatment plan developed specifically for the patient who is insulin-dependent; and motivation for patients to use the new skills for self-management (see § 410.144(a)(5)). DSMT services are reported under HCPCS codes G0108 (Diabetes outpatient self-management training services, individual, per 30 minutes) and G0109 (Diabetes outpatient self-management training services, group session (2 or more), per 30 minutes). The benefit, as specified at § 410.141, consists of 1 hour of individual and 9 hours of group training unless special circumstances warrant more individual training or no group session is available within 2 months of the date the training is ordered.

Section 1861(qq) of the Act specifies that DMST services are furnished by a certified provider, defined as a physician or other individual or entity that also provides, in addition to DSMT, other items or services for which payment may be made under Medicare. The physician, individual or entity that furnishes the training also must meet certain quality standards. The physician, individual or entity can meet standards established by us or standards originally established by the National Diabetes Advisory Board and subsequently revised by organizations who participated in their establishment, or can be recognized by an organization that represents individuals with diabetes as meeting standards for furnishing the services.

We require that all those who furnish DSMT services be accredited as meeting quality standards by a CMS-approved national accreditation organization (NAO). In accordance with § 410.144, a CMS-approved NAO may accredit an individual, physician or entity to meet one of three sets of DSMT quality standards: CMS quality standards; the National Standards for Diabetes Self-Management Education Programs (National Standards); or the standards of an NAO that represents individuals with diabetes that meet or exceed our quality standards. Currently, we recognize the American Diabetes Association and the American Association of Diabetes Educators as approved NAOs, both of whom follow National Standards. Medicare payment for outpatient DSMT services is made in accordance with § 414.63.

An article titled "Use of Medicare's Diabetes Self-Management Training Benefit" was published in the *Health Education Behavior* on January 23, 2015. The article noted that only 5 percent of Medicare beneficiaries with newly diagnosed diabetes used DSMT services. The article recommended that future research identify barriers to DSMT access.

We understand there are a number of issues that may contribute to the low utilization of these services. Some of the issues that have been brought to our attention by the DSMT community and NAOs are:

- Concerns that claims have been rejected or denied because of confusion about the credentials of the individuals who furnish DSMT services. In entities following the National Standards, the credentials of the educators actually providing the training are determined by the NAO and are not to be determined by the Medicare Administrative Contractor. Many individuals who actually furnish DSMT services, such as registered nurses and pharmacists, do not qualify to enroll in Medicare as certified providers, as that term is defined at section 1861(qq)(2)(A) of the Act, and codified in our regulations at § 410.140 as approved entit(ies).
- Questions about when individual (rather than group) DSMT services are available. As noted above, the benefit consists of 1 hour of individual and 9 hours of group training unless special circumstances warrant more individual training or no group session is available within 2 months of the date the training is ordered. The special circumstances are when the beneficiary's physician or qualified NPP documents in the beneficiary's medical record that the beneficiary has special needs resulting from conditions such as severe vision, hearing, or language limitations that would hinder effective participation in a group training session. In all cases, however, the physician or NPP must order individual training.
- Concerns that the Medicare Benefit Policy Manual, Chapter 15, section 300 does not clarify the settings and locations in which DSMT services may be provided. As a result, some providers (and perhaps some Medicare contractors) are confused. In regard to this issue, we note that a forthcoming manual update will reiterate the guidance we provided to the DSMT community, including the NAOs, in a response to their letter requesting clarification regarding the settings and locations in which DSMT services can be provided. The manual update will clarify that: (a) In the case of DSMT services furnished by an entity that submits professional claims to the A/B Medicare Administrative Contractor (MAC), such as a physician's office or an RD's practice, DSMT services may be furnished at alternate locations used by the entity as a practice location; and (b) when the DSMT services are furnished by an entity that is a hospital outpatient department (HOPD), these DSMT services must be furnished in the hospital (including a provider-based department) and cannot be furnished at alternate non-hospital locations. We plan to address and clarify the above issues through Medicare program instructions as appropriate. We also recognize the possibility that Medicare payment for these services may not fully reflect the resources required to provide them and this may be contributing to relatively low utilization. There may also be other barriers to access of which we are not aware. We are seeking public comment on such barriers to help us identify and address them. We also seek comment and information on whether Medicare payment for these services is accurate. In particular, we would appreciate information on the time and intensity of services provided, and on the services and supplies that should be included in the calculation of practice expenses. We will consider this information to determine whether to propose an update to resource inputs used to develop payment rates for these services in future rulemaking.

G. Target for Relative Value Adjustments for Misvalued Services

Section 1848(c)(2)(O) of the Act establishes an annual target for reductions in PFS expenditures resulting from adjustments to relative values of misvalued codes. Under section 1848(c)(2)(O)(ii) of the Act, if the estimated net reduction in expenditures for a year as a result of adjustments to the relative values for misvalued codes is equal to or greater than the target for that year, reduced expenditures attributable to such adjustments shall be redistributed in a budget-neutral manner within the PFS in accordance with the existing budget neutrality requirement under section 1848(c)(2)(B)(ii)(II) of the Act. The provision also specifies that the amount by which such reduced expenditures exceeds the target for a given year shall be treated as a net reduction in expenditures for the succeeding year, for purposes of determining whether the target has been met for that subsequent year. Section 1848(c)(2)(O)(iv) of the Act defines a target recapture amount as the difference between the target for the year and the estimated net reduction in expenditures under the PFS resulting from adjustments to RVUs for misvalued codes. Section 1848(c)(2)(O)(iii) of the Act specifies that, if the estimated net reduction in PFS expenditures for the year is less than the target for the year, an amount equal to the target recapture amount shall not be taken into account when applying the budget neutrality requirements specified in section 1848(c)(2)(B)(ii)(II) of the Act. Under section 1848(c)(2)(O)(v) of the Act, the target that applies to calendar years (CYs) 2017 and 2018 is calculated as 0.5 percent of the estimated amount of expenditures under the PFS for the year.

In CY 2016 PFS rulemaking, we proposed and finalized a methodology to implement this statutory provision.

Because the annual target is calculated by measuring changes from one year to the next, for CY 2016, we considered how to account for changes in values that are best measured over 3 years, instead of 2 years. As we described in the CY 2016 final rule with comment period (80 FR 70932), our general valuation process for potentially misvalued, new, and revised codes was to establish values on an interim final basis for a year in the PFS final rule with comment period. Then, during the 60-day period following the publication of the final rule with comment period, we would accept public comment about those valuations. In the final rule with comment period for the subsequent year, we would consider and respond to public comments received on the interim final values, and make any appropriate adjustments to values based on those comments. Under that process for revaluing new, revised, and misvalued codes, we believe the overall change in valuation for many codes would best measured across values for 3 years: Between the original value in the first year; the interim final value in the second year; and the finalized value in the third year. However, the target calculation for a year would only be comparing changes in RVUs between 2 years and not among 3 years, so the contribution of a particular change towards the target for any single year would be measured against only the preceding year without regard to the overall change that takes place over 3 years.

For recent years, interim final values for misvalued codes (year 2) have generally reflected reductions relative to original values (year 1), and for most codes, the interim final values (year 2) are maintained and finalized (year 3). However, when values for particular codes have changed between the interim final (year 2) and final values (year 3) based on public comment, the general tendency has been that codes increase in the final value (year 3) relative to the interim final value (year 2), even in cases where the final value (year 3) represents a decrease from the original value (year 1). Therefore, for these codes, the year 2 changes compared to year 1 would risk over-representing the overall reduction, while the year 3 to year 2 changes would represent an increase in value. We noted that if there were similar targets in every PFS year, and a similar number of misvalued code changes made on an interim final basis, the incongruence in measuring what is really a 3-year change in 2-year increments might not be particularly problematic since each year's calculation would presumably include a similar number of codes measured between years 1 and 2 and years 2 and 3.

However, including changes that take place over 3 years generated challenges in calculating the target for CY 2016. Because there was no target for CY 2015, any reductions that occurred on an interim final basis for CY 2015 were not counted toward achievement of a target. If we had then included any upward adjustments made to these codes based on public comment as "misvalued code" changes for CY 2016, we would effectively be counting the service-level increases for 2016 (year 3) relative to 2015 (year 2) against achievement of the target without any consideration to the service-level changes relative to 2014 (year 1), even in cases where the overall change in valuation was negative.

Therefore, we proposed and finalized the decision to exclude code-level input changes for CY 2015 interim final values from the calculation of the CY 2016 misvalued code target since the misvalued change occurred over multiple years, including years not applicable to the misvalued code target provision.

For the CY 2017 final rule with comment period, we will be finalizing values (year 3) for codes that were interim final in CY 2016 (year 2). Unlike codes that were interim final for CY 2015, the codes that are interim final for CY 2016 were included as misvalued codes and will fall within the range of years for which the misvalued code target provision applies. Thus, overall changes in values for these codes would be measured in the target across 3 full years: The original value in the first year (CY 2015); the interim final value in the second year (CY 2016); and the finalized value in the third year (CY 2017). The changes in valuation for these CY 2016 interim final codes were previously measured and counted towards the target during their initial change in valuation between years 1 and 2.

As such, we are proposing to include changes in values of the CY 2016 interim final codes toward the CY 2017 misvalued code target. We believe that this is consistent with the approach that we finalized in last year's final rule with comment period. The changes in values of CY 2015 interim final codes were not counted towards the misvalued code target in CY 2016 since the valuation change occurred over multiple years, including years not applicable to the misvalued code target provision. However, both of the changes in valuation for the CY 2016 interim final codes, from year 1 to year 2 (CY 2015 to CY 2016) and from year 2 to year 3 (CY 2016 to CY 2017), have taken place during years that occur within the misvalued code target provision. We therefore believe that any adjustments made to these codes based on public comment should be considered towards the achievement of the target for CY 2017, just as any changes in valuation for these same CY 2016 interim final codes previously counted towards the achievement of the target for CY 2016.

We seek public comments regarding this proposal. We also remind commenters that we have revised our process for revaluing new, revised and misvalued codes so that we will be proposing and finalizing values for most of the misvalued codes during a single calendar year. After this year, there will be far fewer instances of interim final codes and changes that are best measured over 3 years far.

We refer readers to the regulatory impact analysis section of this proposed rule for our estimate of the proposed net reduction in expenditures relative to the 0.5 percent target for CY 2017, and the resulting adjustment required to be made to the conversion factor. Additionally, we refer readers to the public use file that provides a comprehensive description of how the target is calculated as well as the estimated impact by code family on the CMS Web site under the supporting data files for the CY 2017 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html.*

H. Phase-In of Significant RVU Reductions

Section 1848(c)(7) of the Act specifies that for services that are not new or revised codes, if the total RVUs for a service for a year would otherwise be decreased by an estimated 20 percent or more as compared to the total RVUs for the previous year, the applicable adjustments in work, PE, and MP RVUs shall be phased in over a 2-year period.

In the CY 2016 PFS rulemaking, we proposed and finalized a methodology to implement this statutory provision. To determine which services are described by new or revised codes for purposes of the phase-in provision, we apply the phase-in to all services that are described by the same, unrevised code in both the current and update year, and exclude codes that describe different services in the current and update year.

Because the phase-in of significant reductions in RVUs falls within the budget neutrality requirements specified in section 1848(c)(2)(B)(ii)(II) of the Act, we estimate the total RVUs for a service prior to the budget-neutrality redistributions that result from implementing phase-in values. In implementing the phase-in, we consider a 19 percent reduction as the maximum 1-year reduction for any service not described by a new or revised code. This approach limits the year one reduction for the service to the maximum allowed amount (that is, 19 percent), and then phases in the remainder of the reduction.

The statute provides that the applicable adjustments in work, PE, and MP RVUs shall be phased in over a 2-year period when the RVU reduction for a code for a year is estimated to be equal to or greater than 20 percent. Since CY 2016 was the first year in which we applied the phase-in transition, CY 2017 will be the first year in which a single code could be subject to RVU reductions greater than 20 percent for 2 consecutive years.

Under our finalized policy, the only codes that are not subject to the phase-in are those that are new or revised, which we defined as those services that are not described by the same, unrevised code in both the current and update year, or by the same codes that describe different services in the current and update year. Since CY 2016 was the first year for which the phase-in provision applied, we did not address how we would handle codes with values that had been partially phased in during the first year, but that have a remaining phase-in reduction of 20 percent or greater.

The significant majority of codes with reductions in RVUs that are greater than 20 percent in year one would not be likely to meet the 20 percent threshold in a consecutive year. However, in a few cases, significant changes (for example, in the input costs included in the valuation of a service) could produce reductions of 20 percent or greater in consecutive years.

We believe that a consistent methodology regarding the phase-in transition should be applied to these cases. We propose to reconsider in each year, for all codes that are not new or revised codes and including codes that were assigned a phase-in value in the previous year, whether the total RVUs for the service would otherwise be decreased by an estimated 20 percent or more as compared to the total RVUs for the previous year. Under this proposed policy, the 19 percent reduction in total RVUs would continue to be the maximum one-year reduction for all codes (except those considered new and revised), including those codes with phase-in values in the previous year. In other words, for purposes of the 20 percent threshold, every service is evaluated anew each year, and any applicable phase-in is limited to a decrease of 19 percent. For example, if we were to adopt a 50 percent reduction in total RVUs for an individual service, the reduction in any particular year would be limited to a decrease of 19 percent in total RVUs. Because we do not set rates 2 years in advance, the phase-in transition continues to apply until the year-to-year reduction for a given code does not meet the 20 percent threshold.

We are soliciting comments regarding this proposal.

The list of codes proposed to be subject to the phase-in and the associated proposed RVUs that result from this methodology are available on the CMS Web site under downloads for the CY 2017 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.*

I. Geographic Practice Cost Indices (GPCIs)

1. Background

Section 1848(e)(1)(A) of the Act requires us to develop separate Geographic Practice Cost Indices (GPCIs) to measure relative cost differences among localities compared to the national average for each of the three fee schedule components (that is, work, PE, and malpractice (MP)). The PFS localities are discussed in section II.E.3. of this proposed rule. Although the statute requires that the PE and MP GPCIs reflect the full relative cost differences, section 1848(e)(1)(A)(iii) of the Act requires that the work GPCIs reflect only one-quarter of the relative cost differences compared to the national average. In addition, section 1848(e)(1)(G) of the Act sets a permanent 1.5 work GPCI floor for services furnished in Alaska beginning January 1, 2009, and section 1848(e)(1)(I) of the Act sets a permanent 1.0 PE GPCI floor for services furnished in frontier states (as defined in section 1848(e)(1)(I) of the Act) beginning January 1, 2011. Additionally, section 1848(e)(1)(E) of the Act provided for a 1.0 floor for the work GPCIs, which was set to expire on March 31, 2015. Section 201 of the MACRA amended the statute to extend the 1.0 floor for the work GPCIs through CY 2017 (that is, for services furnished no later than December 31, 2017).

Section 1848(e)(1)(C) of the Act requires us to review and, if necessary, adjust the GPCIs at least every 3 years. Section 1848(e)(1)(C) of the Act requires that, if more than 1 year has elapsed since the date of the last previous GPCI adjustment, the adjustment to be applied in the first year of the next adjustment shall be half of the adjustment that otherwise would be made. Therefore, since the previous GPCI update was implemented in CY 2014 and CY 2015, we are proposing to phase in 1/2 of the latest GPCI adjustment in CY 2017.

We have completed a review of the GPCIs and are proposing new GPCIs in this proposed rule. We also calculate a geographic adjustment factor (GAF) for each PFS locality. The GAFs are a weighted composite of each area's work, PE and malpractice expense GPCIs using the national GPCI cost share weights. While we do not actually use GAFs in computing the fee schedule payment for a specific service, they are useful in comparing overall areas costs and payments. The actual effect on payment for any actual service would deviate from the GAF to the extent that the proportions of work, PE and MP RVUs for the service differ from those of the GAF.

As noted above, section 201 of the MACRA extended the 1.0 work GPCI floor for services furnished through December 31, 2017. Therefore, the proposed CY 2017 work GPCIs and summarized GAFs reflect the 1.0 work floor. Additionally, as required by sections 1848(e)(1)(G) and 1848(e)(1)(I) of the Act, the 1.5 work GPCI floor for Alaska and the 1.0 PE GPCI floor for frontier states are permanent, and therefore, applicable in CY 2017. See Addenda D and E to this proposed rule for the proposed CY 2017 GPCIs and summarized GAFs available on the CMS Web site under the supporting documents section of the CY 2017 PFS proposed rule located at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html.*

2. GPCI Update

The proposed updated GPCI values were calculated by a contractor. There are three GPCIs (work, PE, and MP), and all GPCIs are calculated through comparison to a national average for each. Additionally, each of the three GPCIs relies on its own data source(s) and methodology for calculating its value as described below. Additional information on the CY 2017 GPCI update may be found in our contractor's draft report, "Draft Report on the CY 2017 Update of the Geographic Practice Cost Index for the Medicare Physician Fee Schedule," which is available on our Web site. It is located under the supporting documents section for the CY 2017 PFS proposed rule located at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html.*

a. Work GPCIs

The work GPCIs are designed to reflect the relative costs of physician labor by Medicare PFS locality. As required by statute, the work GPCI reflects one quarter of the relative wage differences for each locality compared to the national average.

To calculate the work GPCIs, we use wage data for seven professional specialty occupation categories, adjusted to reflect one-quarter of the relative cost differences for each locality compared to the national average, as a proxy for physicians' wages. Physicians' wages are not included in the occupation categories used in calculating the work GPCI because Medicare payments are a key determinant of physicians' earnings. Including physician wage data in calculating the work GPCIs would potentially introduce some circularity to the adjustment since Medicare payments typically contribute to or influence physician wages. That is, including physicians' wages in the physician work GPCIs would, in effect, make the indices, to some extent, dependent upon Medicare payments.

The work GPCI updates in CYs 2001, 2003, 2005, and 2008 were based on professional earnings data from the 2000 Census. However, for the CY 2011 GPCI update (75 FR 73252), the 2000 data were outdated and wage and earnings data were not available from the more recent Census because the "long form" was discontinued. Therefore, we used the median hourly earnings from the 2006 through 2008 Bureau of Labor Statistics (BLS) Occupational Employment Statistics (OES) wage data as a replacement for the 2000 Census data. The BLS OES data meet several criteria that we consider to be important for selecting a data source for purposes of calculating the GPCIs. For example, the BLS OES wage and employment data are derived from a large sample size of approximately 200,000 establishments of varying sizes nationwide from every metropolitan area and can be easily accessible to the public at no cost. Additionally, the BLS OES is updated regularly, and includes a comprehensive set of occupations and industries (for example, 800 occupations in 450 industries). For the CY 2014 GPCI update, we used updated BLS OES data (2009 through 2011) as a replacement for the 2006 through 2008 data to compute the work GPCIs.

Because of its reliability, public availability, level of detail, and national scope, we believe the BLS OES continues to be the most appropriate source of wage and employment data for use in calculating the work GPCIs (and as discussed in section II.E.2.b the employee wage component and purchased services component of the PE GPCI). Therefore, for the proposed CY 2017 GPCI update, we used updated BLS OES data (2011 through 2014) as a replacement for the 2009 through 2011 data to compute the work GPCIs.

b. Practice Expense GPCIs

The PE GPCIs are designed to measure the relative cost difference in the mix of goods and services comprising practice expenses (not including malpractice expenses) among the PFS localities as compared to the national average of these costs. Whereas the physician work GPCIs (and as discussed later in this section, the MP GPCIs) are comprised of a single index, the PE GPCIs are comprised of four component indices (employee wages; purchased services; office rent; and equipment, supplies and other miscellaneous expenses). The employee wage index component measures geographic variation in the cost of the kinds of skilled and unskilled labor that would be directly employed by a physician practice. Although the employee wage index adjusts for geographic variation in the cost of labor employed directly by physician practices, it does not account for geographic variation in the cost of services that typically would be purchased from other entities, such as law firms, accounting firms, information technology consultants, building service managers, or any other third-party vendor. The purchased services index component of the PE GPCI (which is a separate index from employee wages) measures geographic variation in the cost of contracted services that physician practices would typically buy. (For more information on the development of the purchased service index, we refer readers to the CY 2012 PFS final rule with comment period (76 FR 73084 through 73085)). The office rent index component of the PE GPCI measures relative geographic variation in the cost of typical physician office rents. For the medical equipment, supplies, and miscellaneous expenses component, we believe there is a national market for these items such that there is not significant geographic variation in costs. Therefore, the equipment, supplies and other miscellaneous expense cost index component of the PE GPCI is given a value of 1.000 for each PFS locality.

For the previous update to the GPCIs (implemented in CY 2014) we used 2009 through 2011 BLS OES data to calculate the employee wage and purchased services indices for the PE GPCI. As discussed in section II.E.2.a., because of its reliability, public availability, level of detail, and national scope, we continue to believe the BLS OES is the most appropriate data source for collecting wage and employment data. Therefore, in calculating the proposed CY 2017 GPCI update, we used updated BLS OES data (2011 through 2014) as a replacement for the 2009 through 2011 data for purposes of calculating the employee wage component and purchased service index of the PE GPCI.

c. Malpractice Expense (MP) GPCIs

The MP GPCIs measure the relative cost differences among PFS localities for the purchase of professional liability insurance (PLI). The MP GPCIs are calculated based on insurer rate filings of premium data for $1 million to $3 million mature claims-made policies (policies for claims made rather than services furnished during the policy term). For the CY 2014 GPCI update (seventh update) we used 2011 and 2012 malpractice premium data (78 FR 74382). The proposed CY 2017 MP GPCI update reflects 2014 and 2015 premium data. Additionally, the proposed CY 2017 MP GPCI update reflects several proposed technical refinements to the MP GPCI methodology as discussed later in section 5.

d. GPCI Cost Share Weights

For the proposed CY 2017 GPCIs, we are continuing to use the current cost share weights for determining the PE GPCI values and locality GAFs. We refer readers to the CY 2014 PFS final rule with comment period (78 FR 74382 through 74383), for further discussion regarding the 2006-based MEI cost share weights revised in CY 2014 that were also finalized for use in the CY 2014 (seventh) GPCI update.

The proposed GPCI cost share weights for CY 2017 are displayed in Table 12.

TABLE 12—PROPOSED COST SHARE WEIGHTS FOR CY 2017 GPCI UPDATE

Expense category	Current cost share weight (%)	Proposed CY 2017 cost share weight (%)
Work	50.866	50.866
Practice Expense	44.839	44.839
—Employee Compensation	16.553	16.553
—Office Rent	10.223	10.223
—Purchased Services	8.095	8.095
—Equipment, Supplies, Other	9.968	9.968
Malpractice Insurance	4.295	4.295
Total	100.000	100.000

e. PE GPCI Floor for Frontier States

Section 10324(c) of the Affordable Care Act added a new subparagraph (I) under section 1848(e)(1) of the Act to establish a 1.0 PE GPCI floor for physicians' services furnished in frontier states effective January 1, 2011. In accordance with section 1848(e)(1)(I) of the Act, beginning in CY 2011, we applied a 1.0 PE GPCI floor for physicians' services furnished in states determined to be frontier states. In general, a frontier state is one in which at least 50 percent of the counties are "frontier counties," which are those that have a population per square mile of less than 6. For more information on the criteria used to define a frontier state, we refer readers to the FY 2011 Inpatient Prospective Payment System (IPPS) final rule (75 FR 50160 through 50161). There are no changes in the states identified as Frontier States for the CY 2017 proposed rule. The qualifying states are: Montana, Wyoming, North Dakota, South Dakota, and Nevada. In accordance with statute, we would apply a 1.0 PE GPCI floor for these states in CY 2017.

f. Proposed GPCI Update

As explained above in the background section, the periodic review and adjustment of GPCIs is mandated by section 1848(e)(1)(C) of the Act. At each update, the proposed GPCIs are published in the PFS proposed rule to provide an opportunity for public comment and further revisions in response to comments prior to implementation. The proposed CY 2017 updated GPCIs for the first and second year of the 2-year transition, along with the GAFs, are displayed in Addenda D and E to this proposed rule available on our Web site under the supporting documents section of the CY 2017 PFS proposed rule Web page at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html.*

3. Payment Locality Discussion

a. Background

The current PFS locality structure was developed and implemented in 1997. There are currently 89 total PFS localities; 34 localities are statewide areas (that is, only one locality for the entire state). There are 52 localities in the other 16 states, with 10 states having 2 localities, 2 states having 3 localities, 1 state having 4 localities, and 3 states having 5 or more localities. The combined District of Columbia, Maryland, and Virginia suburbs; Puerto Rico; and the Virgin Islands are the remaining three localities of the total of 89 localities. The development of the current locality structure is described in detail in the CY 1997 PFS proposed rule (61 FR 34615) and the subsequent final rule with comment period (61 FR 59494). We note that the localities generally represent a grouping of one or more constituent counties.

Prior to 1992, Medicare payments for physicians' services were made under the reasonable charge system. Payments were based on the charging patterns of physicians. This resulted in large differences in payment for physicians' services among types of services, geographic payment areas, and physician specialties. Recognizing this, the Congress replaced the reasonable charge system with the Medicare PFS in the Omnibus Budget Reconciliation Act (OBRA) of 1989, and the PFS went into effect January 1, 1992. Payments under the PFS are based on the relative resources involved with furnishing services, and are adjusted to account for geographic variations in resource costs as measured by the GPCIs.

Payment localities originally were established under the reasonable charge system by local Medicare carriers based on their knowledge of local physician charging patterns and economic conditions. These localities changed little between the inception of Medicare in 1967 and the beginning of the PFS in 1992. Shortly after the PFS took effect, we undertook a study in 1994 that culminated in a comprehensive locality revision that was implemented in 1997 (61 FR 59494).

The revised locality structure reduced the number of localities from 210 to the current 89, and the number of statewide localities increased from 22 to 34. The revised localities were based on locality resource cost differences as reflected by the GPCIs. For a full discussion of the methodology, see the CY 1997 PFS final rule with comment period (61 FR 59494). The current 89 fee schedule areas are defined alternatively by state boundaries (for example, Wisconsin), metropolitan areas (for example, Metropolitan St. Louis, MO), portions of a metropolitan area (for example, Manhattan), or rest-of-state areas that exclude metropolitan areas (for example, Rest of Missouri). This locality configuration is used to calculate the GPCIs that are in turn used to calculate payments for physicians' services under the PFS.

As stated in the CY 2011 PFS final rule with comment period (75 FR 73261), changes to the PFS locality structure would generally result in changes that are budget neutral within a state. For many years, before making any locality changes, we have sought consensus from among the professionals whose payments would be affected. In recent years, we have also considered more comprehensive changes to locality configuration. In 2008, we issued a draft comprehensive report detailing four different locality configuration options (*https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/downloads/ReviewOfAltGPCIs.pdf*). We refer readers to the CY 2014 PFS final rule with comment period for further discussion regarding that report, as well as a discussion about the Institute of Medicine's empirical study of the Medicare GAFs established under sections 1848(e) (PFS GPCI) and 1886(d)(3)(E) (IPPS wage index) of the Act.

b. California Locality Update to the Fee Schedule Areas Used for Payment Under Section 220(h) of the Protecting Access to Medicare Act

(1) General Discussion and Legislative Change

Section 220(h) of the PAMA added a new section 1848(e)(6) to the Act, that modifies the fee schedule areas used for payment purposes in California beginning in CY 2017.

Currently, the fee schedule areas used for payment in California are based on the revised locality structure that was implemented in 1997 as previously discussed. Beginning in CY 2017, section 1848(e)(6)(A)(i) of the Act requires that the fee schedule areas used for payment in California must be Metropolitan Statistical Areas (MSAs) as defined by the Office of Management and Budget (OMB) as of December 31 of the previous year; and section 1848(e)(6)(A)(ii) of the Act requires that all areas not located in an MSA must be treated as a single rest-of-state fee schedule area. The resulting modifications to California's locality structure would increase its number of localities from 9 under the current locality structure to 27 under the MSA-based locality structure.

However, section 1848(e)(6)(D) of the Act defines transition areas as the fee schedule areas for 2013 that were the rest-of-state locality, and locality 3, which was comprised of Marin county, Napa county, and Solano county. Section 1848(e)(6)(B) specifies that the GPCI values used for payment in a transition area are to be phased in over 6 years, from 2017 through 2021, using a weighted sum of the GPCIs calculated under the new MSA-based locality structure and the GPCIs calculated under the current PFS locality structure. That is, the GPCI values applicable for these areas during this transition period are a blend of what the GPCI values would have been under the current locality structure, and what the GPCI values would be under the MSA-based locality structure. For example, in the first year, CY 2017, the applicable GPCI values for counties that were previously in rest-of-state or locality 3 and are now in MSAs are a blend of 1/6 of the GPCI value calculated for the year under the MSA-based locality structure, and 5/6 of the GPCI value calculated for the year under the current locality structure. The proportions shift by 1/6 in each subsequent year so that, by CY 2021, the applicable GPCI values for counties within transition areas are a blend of 5/6 of the GPCI value for the year under the MSA-based locality structure, and 1/6 of the GPCI value for the year under the current locality structure. Beginning in CY 2022, the applicable GPCI values for counties in transition areas are the values calculated under the new MSA-based locality structure. For the sake of clarity, we reiterate that this incremental phase-in is only applicable to those counties that are in transition areas that are now in MSAs, which are only some of the counties in the 2013 California rest-of state locality and locality 3.

Additionally, section 1848(e)(6)(C) of the Act establishes a hold harmless for transition areas beginning with CY 2017 whereby the applicable GPCI values for a year under the new MSA-based locality structure may not be less than what they would have been for the year under the current locality structure. There are a total of 58 counties in California, 50 of which are in transition areas as defined in section 1848(e)(6)(D) of the Act. Therefore, 50 counties in California are subject to the hold harmless provision. The other 8 counties, which are metropolitan counties that are not defined as transition areas, are not held harmless for the impact of the new MSA-based locality structure, and may therefore potentially experience slight decreases in their GPCI values as a result of the provisions in section 1848(e)(6) of the Act, insofar as the locality in which they are located now newly includes data from adjacent counties that decreases their GPCI values relative to those that would have applied had the new data not been incorporated. Therefore, the GPCIs for these eight counties under the MSA-based locality structure may be less than they would have been under the current GPCI structure. The eight counties that are not within transition areas are: Orange; Los Angeles; Alameda; Contra Costa; San Francisco; San Mateo; Santa Clara; and Ventura counties.

We emphasize that while transition areas are held harmless from the impact of the GPCI changes using the new MSA-based locality structure, because we are proposing other updates for CY 2017 as part of the eighth GPCI update, including the use of updated data, transition areas would still be subject to impacts resulting from those other updates. Table 13 illustrates using GAFs, for CY 2017, the isolated impact of the MSA-based locality changes and hold-harmless for transition areas required by section 1848(e)(6) of the Act, the impact of the proposed use of updated data for GPCIs, and the combined impact of both of these proposed changes.

TABLE 13—IMPACT ON CALIFORNIA GAFS AS A RESULT OF SECTION 1848(e)(6) OF THE ACT AND PROPOSED UPDATED DATA BY FEE SCHEDULE AREA

[Sorted alphabetically by locality name]

Medicare fee schedule area	Transition area	2016 GAF	2017 GAF w/o 1848(e)(6)	% Change due to new GPCI data	2017 GAF w/ 1848(e)(6)	% Change due to 1848(e)(6)	Combined impact of PAMA and new GPCI data (%)
Bakersfield	1	1.04	1.031	−0.50	1.031	0.00	−0.50
Chico	1	1.04	1.031	−0.50	1.031	0.00	−0.50
El Centro	1	1.04	1.031	−0.50	1.031	0.00	−0.50
Fresno	1	1.04	1.031	−0.50	1.031	0.00	−0.50
Hanford-Corcoran	1	1.04	1.031	−0.50	1.031	0.00	−0.50
Los Angeles-Long Beach-Anaheim (Los Angeles County)	0	1.09	1.09	−0.20	1.091	0.10	−0.10
Los Angeles-Long Beach-Anaheim (Orange County)	0	1.09	1.104	1.10	1.101	−0.30	0.80
Madera	1	1.04	1.031	−0.50	1.031	0.00	−0.50
Merced	1	1.04	1.031	−0.50	1.031	0.00	−0.50
Modesto	1	1.04	1.031	−0.50	1.031	0.00	−0.50
Napa	1	1.14	1.128	−0.80	1.128	0.00	−0.80
Oxnard-Thousand Oaks-Ventura	0	1.09	1.083	−0.60	1.083	0.00	−0.60
Redding	1	1.04	1.031	−0.50	1.031	0.00	−0.50
Rest Of California	1	1.04	1.031	−0.50	1.031	0.00	−0.50
Riverside-San Bernardino-Ontario	1	1.04	1.031	−0.50	1.032	0.10	−0.40
Sacramento-Roseville-Arden-Arcade	1	1.04	1.031	−0.50	1.031	0.00	−0.50
Salinas	1	1.04	1.031	−0.50	1.033	0.20	−0.30
San Diego-Carlsbad	1	1.04	1.031	−0.50	1.035	0.40	−0.10
San Francisco-Oakland-Hayward (Alameda/Contra Costa County)	0	1.18	1.125	−4.80	1.142	1.50	−3.40
San Francisco-Oakland-Hayward (Marin County)	1	1.14	1.128	−0.80	1.129	0.10	−0.70
San Francisco-Oakland-Hayward (San Francisco County)	0	1.18	1.194	1.00	1.175	−1.60	−0.60
San Francisco-Oakland-Hayward (San Mateo County)	0	1.18	1.187	0.40	1.171	−1.30	−0.90
San Jose-Sunnyvale-Santa Clara (San Benito County)	1	1.04	1.031	−0.50	1.053	2.10	1.60
San Jose-Sunnyvale-Santa Clara (Santa Clara County)	0	1.18	1.176	0.10	1.175	−0.10	0.00

TABLE 13—IMPACT ON CALIFORNIA GAFs AS A RESULT OF SECTION 1848(e)(6) OF THE ACT AND PROPOSED UPDATED DATA BY FEE SCHEDULE AREA—Continued

[Sorted alphabetically by locality name]

Medicare fee schedule area	Transition area	2016 GAF	2017 GAF w/o 1848(e)(6)	% Change due to new GPCI data	2017 GAF w/ 1848(e)(6)	% Change due to 1848(e)(6)	Combined impact of PAMA and new GPCI data (%)
San Luis Obispo-Paso Robles-Arroyo Grande	1	1.04	1.031	−0.50	1.031	0.00	−0.50
Santa Cruz-Watsonville	1	1.04	1.031	−0.50	1.042	1.10	0.60
Santa Maria-Santa Barbara	1	1.04	1.031	−0.50	1.036	0.50	0.00
Santa Rosa	1	1.04	1.031	−0.50	1.037	0.60	0.10
Stockton-Lodi	1	1.04	1.031	−0.50	1.031	0.00	−0.50
Vallejo-Fairfield	1	1.14	1.128	−0.80	1.128	0.00	−0.80
Visalia-Porterville	1	1.04	1.031	−0.50	1.031	0.00	−0.50
Yuba City	1	1.04	1.031	−0.50	1.031	0.00	−0.50

Additionally, for the purposes of calculating budget neutrality and consistent with the PFS budget neutrality requirements as specified under section 1848(c)(2)(B)(ii)(II) of the Act, we are proposing to start by calculating the national GPCIs as if the current localities are still applicable nationwide; then for the purposes of payment in California, we will override the GPCI values with the values that are applicable for California consistent with the requirements of section 1848(e)(6) of the Act. This approach is consistent with the implementation of the GPCI floor provisions that have previously been implemented—that is, as an after-the-fact adjustment that is implemented for purposes of payment after both the GPCIs and PFS budget neutrality have already been calculated.

(2) Proposed Operational Considerations

As discussed above, under section 1848(e)(6) of the Act, counties that were previously in the rest-of-state locality or locality 3 and are now in MSAs would have their GPCI values under the new MSA-based locality structure phased in gradually, in increments of one-sixth over 6 years. Section 1848(e)(1)(C) of the Act requires that, if more than 1 year has elapsed since the date of the last previous GPCI adjustment, the adjustment to be applied in the first year of the next adjustment shall be 1/2 of the adjustment that otherwise would be made. While section 1848(e)(6)(B) of the Act establishes a blended phase-in for the MSA-based GPCI values, it does not explicitly state whether or how that provision is to be reconciled with the requirement at section 1848(e)(1)(C) of the Act. We believe that since section 1848(e)(6)(A) of the Act requires that we must make the change to MSA-based fee schedule areas for California GPCIs notwithstanding the preceding provisions of section 1848(e) of the Act, and subject to the succeeding provisions of section 1848(e)(6) of the Act, that applying the two-year phase-in specified by the preceding provisions simultaneously with the six-year phase-in would undermine the incremental 6-year phase-in specified in section 1848(e)(6)(B) of the Act. Therefore, we are proposing that the requirement at section 1848(e)(1)(C) of the Act to phase in ½ of the adjustment in year 1 of the GPCI update would not apply to counties that were previously in the rest-of-state or locality 3 and are now in MSAs, and therefore, are subject to the blended phase-in as described above. Since section 1848(e)(6)(B) of the Act provides for a gradual phase in of the GPCI values under the new MSA-based locality structure, specifically in one-sixth increments over 6 years, if we were to also apply the requirement to phase in 1/2 of the adjustment in year 1 of the GPCI update then the first year increment would effectively be one-twelfth. We note that this issue is only of concern if more than 1 year has elapsed since the previous GPCI update, and would only be applicable through CY 2021 since, beginning in CY 2022, the GPCI values for such areas in an MSA would be fully based on the values calculated under the new MSA-based locality structure for California.

As previously stated, the resulting modifications to California's locality structure increase its number of localities from 9 under the current locality structure to 27 under the MSA-based locality structure. However, both the current localities and the MSA-based localities are comprised of various component counties, and in some localities only some of the component counties are subject to the blended phase-in and hold harmless provisions required by section 1848(e)(6)(B) and (C) of the Act. Therefore, the application of these provisions may produce differing GPCI values among counties within the same fee schedule area under the MSA-based locality structure. For example, the MSA-based San Jose-Sunnyvale-Santa Clara locality, is comprised of 2 constituent counties—San Benito county, and Santa Clara county. San Benito County is in a transition area (2013 rest-of-state), while Santa Clara county is not. Hence, although the counties are in the same MSA, the requirements of section 1848(e)(6)(B) and (C) of the Act may produce differing GPCI values for each county. To address this issue, we propose to assign a unique locality number to the counties that would be impacted in the aforementioned manner. As a result, although the modifications to California's locality structure increase the number of localities from 9 under the current locality structure to 27 under the MSA-based locality structure, for purposes of payment, the actual number of localities under the MSA-based locality structure would be 32 to account for instances where unique locality numbers are needed as described above. Additionally, while the fee schedule area names are consistent with the MSAs designated by OMB, we are proposing to maintain 2-digit locality numbers to correspond to the existing fee schedule areas. Pursuant to the implementation of the new MSA-based locality structure for California, the total number of PFS localities would increase from 89 to 112. Table 14 displays the current fee schedule areas in California, and Table 15 displays the MSA-based fee schedule areas in California required by section 1848(e)(6) of the Act. Additional information on the California locality update may be found in our contractor's draft report, "Draft Report on the CY 2017 Update of the Geographic Practice Cost Index for the Medicare Physician Fee Schedule," which is available on the CMS Web site.

It is located under the supporting documents section of the CY 2017 PFS proposed rule located at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html.*

TABLE 14—CURRENT FEE SCHEDULE AREAS IN CALIFORNIA

[Sorted alphabetically by locality name]

Locality number	Fee schedule area	Counties
26	Anaheim/Santa Ana.	Orange
18	Los Angeles	Los Angeles
03	Marin/Napa/Solano.	Marin, Napa, And Solano
07	Oakland/Berkley.	Alameda And Contra Costa
05	San Francisco	San Francisco
06	San Mateo	San Mateo
09	Santa Clara	Santa Clara
17	Ventura	Ventura
99	Rest Of State ..	All Other Counties

TABLE 15—MSA-BASED FEE SCHEDULE AREAS IN CALIFORNIA

[Sorted alphabetically by locality name]

Current locality number	Proposed new locality number	Fee schedule area (MSA name)	Counties	Transition area
99	54	Bakersfield, CA	Kern	YES.
99	55	Chico, CA	Butte	YES.
99	71	El Centro, CA	Imperial	YES.
99	56	Fresno, CA	Fresno	YES.
99	57	Hanford-Corcoran, CA	Kings	YES.
18	18	Los Angeles-Long Beach-Anaheim, CA *(Los Angeles County).*	Los Angeles	NO.
26	26	Los Angeles-Long Beach-Anaheim, CA *(Orange County)* ...	Orange	NO.
99	58	Madera, CA	Madera	YES.
99	59	Merced, CA	Merced	YES.
99	60	Modesto, CA	Stanislaus	YES.
3	51	Napa, CA	Napa	YES.
17	17	Oxnard-Thousand Oaks-Ventura, CA	Ventura	NO.
99	61	Redding, CA	Shasta	YES.
99	75	REST OF STATE	All Other Counties	YES.
99	62	Riverside-San Bernardino-Ontario, CA	Riverside, and San Bernardino	YES.
99	63	Sacramento—Roseville—Arden-Arcade, CA	El Dorado, Placer, Sacramento, and Yolo.	YES.
99	64	Salinas, CA	Monterey	YES.
99	72	San Diego-Carlsbad, CA	San Diego	YES.
7	7	San Francisco-Oakland-Hayward, CA *(Alameda County/Contra Costa County).*	Alameda, Contra Costa	NO.
3	52	San Francisco-Oakland-Hayward, CA *(Marin County)*	Marin	YES.
5	5	San Francisco-Oakland-Hayward, CA *(San Francisco County).*	San Francisco	NO.
6	6	San Francisco-Oakland-Hayward, CA *(San Mateo County)*	San Mateo	NO.
99	65	San Jose-Sunnyvale-Santa Clara, CA *(San Benito County)*	San Benito	YES.
9	9	San Jose-Sunnyvale-Santa Clara, CA *(Santa Clara County).*	Santa Clara	NO.
99	73	San Luis Obispo-Paso Robles-Arroyo Grande, CA	San Luis Obispo	YES.
99	66	Santa Cruz-Watsonville, CA	Santa Cruz	YES.
99	74	Santa Maria-Santa Barbara, CA	Santa Barbara	YES.
99	67	Santa Rosa, CA	Sonoma	YES.
99	73	Stockton-Lodi, CA	San Joaquin	YES.
3	53	Vallejo-Fairfield, CA	Solano	YES.
99	69	Visalia-Porterville, CA	Tulare	YES.
99	70	Yuba City, CA	Sutter, and Yuba	YES.

4. Proposed Update to the Methodology for Calculating GPCIs in the U.S. Territories

In calculating GPCIs within U.S. states, we use county-level wage data from the Bureau of Labor Statistics (BLS) Occupational Employment Statistics Survey (OES), county-level residential rent data from the American Community Survey (ACS), and malpractice insurance premium data from state departments of insurance. In calculating GPCIs for the U.S. territories, we currently use three distinct methodologies—one for Puerto Rico, another for the Virgin Islands, and a third for the Pacific Islands (Guam, American Samoa, and Northern Marianas Islands). These three methodologies were adopted at different times based primarily on the data that were available at the time they were adopted. At present, because Puerto Rico is the only territory where county-level BLS OES, county-level ACS, and malpractice premium data are available, it is the only territory for which we use territory-specific data to calculate GPCIs. For the Virgin Islands, because county-level wage and rent data are not available, and insufficient malpractice premium data are available, CMS has set the work, PE, and MP GPCI values for the Virgin Islands payment locality at the national average of 1.0 even though, like Puerto Rico, the Virgin Islands is its own locality and county-level BLS OES data are available for the Virgin Islands. For the U.S. territories in the Pacific Ocean, we currently crosswalk GPCIs from the Hawaii locality for each of the three GPCIs, and incorporate no local data from these territories into the GPCI calculations even though county-level BLS OES data does exist for Guam, but not for American Samoa or the Northern Mariana Islands.

As noted above, currently Puerto Rico is the only territory for which we calculate GPCIs using the territory-specific information relative to data from the U.S. States. For several years stakeholders in Puerto Rico have raised concerns regarding the applicability of the proxy data in Puerto Rico relative to their applicability in the U.S. states. We believe that these concerns may be consistent across island territories, but lack of available, appropriate data has made it difficult to quantify such variation in costs. For example, some stakeholders previously indicated that shipping and transportation expenses increase the cost of acquiring medical equipment and supplies in islands and territories relative to the mainland. While we have previously attempted to locate data sources specific to geographic variation in such shipping costs, we found no comprehensive national data source for this information (we refer readers to 78 FR 74387 through 74388 for the detailed discussion of this issue). Therefore, we have not been able to quantify variation in costs specific to island territories in the calculation of the GPCIs.

For all the island territories other than Puerto Rico, the lack of comprehensive data about unique costs for island territories has had minimal impact on GPCIs because we have used either the Hawaii GPCIs (for the Pacific territories) or used the unadjusted national averages (for the Virgin Islands). In an effort to provide greater consistency in the calculation of GPCIs given the lack of comprehensive data regarding the validity of applying the proxy data used in the States in accurately accounting for variability of costs for these island territories, we are proposing to treat the Caribbean Island territories (the Virgin Islands and Puerto Rico) in a consistent manner. We propose to do so by assigning the national average of 1.0 to each GPCI index for both Puerto Rico and the Virgin Islands. We are not proposing any changes to the GPCI methodology for the Pacific Island territories (Guam, American Samoa, and Northern Marianas Islands) where we already consistently assign the Hawaii GPCI values for each of the three GPCIs.

Additional information on the Proposed Update to the Methodology for Calculating GPCIs in the U.S. Territories may be found in our contractor's draft report, "Draft Report on the CY 2017 Update of the Geographic Practice Cost Index for the Medicare Physician Fee Schedule," which is available on our Web site. It is located under the supporting documents section of the CY 2017 PFS proposed rule located at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html.*

5. Proposed Refinement to the MP GPCI Methodology

In the process of calculating MP GPCIs for the purposes of this proposed rule, we identified several technical refinements to the methodology that yield improvements over the current method. We are also proposing refinements that conform to our proposed methodology for calculating the GPCIs for the U.S. Territories described above. Specifically, we are proposing modifications to the methodology to account for missing data used in the calculation of the MP GPCI. Under the methodology used in the CY 2014 GPCI update (78 FR 74380 through 74391), we first calculated the average premiums by insurer and specialty, then imputed premium values for specialties for which we did not have specific data, before adjusting the specialty-specific premium data by market share weights. We are proposing to revise our methodology to instead calculate the average premiums for each specialty using issuer market share for only available companies. This proposed methodological improvement would reduce potential bias resulting from large amounts of imputation, an issue that is prevalent for insurers that only write policies for ancillary specialties for which premiums tend to be low. The current method would impute the low premiums for ancillary specialties across the remaining specialties, and generally greater imputation leads to less accuracy. Additional information on the MP GPCI methodology, and the proposed refinement to the MP GPCI methodology may be found in our contractor's draft report, "Draft Report on the CY 2017 Update of the Geographic Practice Cost Index for the Medicare Physician Fee Schedule," which is available on our Web site. It is located under the supporting documents section of the CY 2017 PFS proposed rule located at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html.*

J. Payment Incentive for the Transition From Traditional X-Ray Imaging to Digital Radiography and Other Imaging Services

Section 502(a)(1) of the Consolidated Appropriations Act of 2016 (H.R. 2029) amended section 1848(b) of the Act by establishing new paragraph (b)(9). Effective for services furnished beginning January 1, 2017, section 1848(b)(9)(A) of the Act reduces by 20 percent the payment amounts under the PFS for the technical component (TC) (including the TC portion of a global service) of imaging services that are X-rays taken using film. The reduction is made prior to any other adjustment under this section and without application of this new paragraph.

Section 1848(b)(9)(B) of the Act provides for a 7 percent reduction in payments for imaging services made under the PFS that are X-rays (including the X-ray component of a packaged service) taken using computed radiology furnished during CY 2018, 2019, 2020, 2021, or 2022, and for a 10 percent reduction for such imaging services taken using computed radiology furnished during CY 2023 or a subsequent year. Computed radiology technology is defined for purposes of this paragraph as cassette-based imaging, which utilizes an imaging plate to create the image involved. Section 1848(b)(9) of the Act also requires implementation of the reductions in payment for X-rays through appropriate mechanisms, which can include the use of modifiers. In accordance with section 1848(c)(2)(B)(v)(X), the adjustments under section 1848(b)(9)(A) of the Act are exempt from budget neutrality.

In this section of the rule, we discuss the proposed implementation of the reduction in payment for X-rays taken using film provided for in section 1848(b)(9)(A) of the Act. Because the required reductions in PFS payment for imaging services (including the imaging portion of a service) that are X-rays taken using computed radiography technology does not apply for CY 2017, we will address implementation of section 1848(b)(9)(B) of the Act in future rulemaking.

To implement the provisions of sections 1848(b)(9)(A) of the Act relating to the PFS payment reduction for X-rays taken using film that are furnished during CY 2017 or subsequent years, in this proposed rule, we are proposing to establish a new modifier (modifier "XX") to be used on claims, as allowed under the section 1848(b)(9)(D) of the Act. The list of CY 2017 applicable HCPCS codes describing imaging services that are X-ray services are on the CMS Web site under downloads for the CY 2017 PFS proposed rule with comment period at *http://www.cms.gov/physicianfeesched/downloads/*. We are proposing that, beginning January 1, 2017, this modifier would be required on claims for X-rays that are taken using film. The modifier would be required on claims for the technical component of the X-ray service, including when the service is billed globally, since the PFS payment adjustment is made to the technical component regardless of whether it is billed globally or separately using the –TC modifier. The use of this proposed modifier to indicate an X-ray taken using film would result in a 20-percent reduction for the technical component of the X-ray service, as specified under section 1848(b)(9)(A) of the Act that would be exempt from budget neutrality as specified under section 1848(c)(2)(B)(v)(X) of the Act.

K. Procedures Subject to the Multiple Procedure Payment Reduction (MPPR) and the OPPS Cap

Effective January 1, 2012, we implemented an MPPR of 25 percent on the professional component (PC) of advanced imaging services. The reduction applies when multiple imaging procedures are furnished by the same physician (or physician in the same group practice) to the same patient, in the same session, on the same day. Full payment is made for the PC of the highest priced procedure. Payment for the PC of subsequent services is reduced by 25 percent.

Section 502(a)(2)(A) of the Consolidated Appropriations Act, 2016 (Pub. L. 114–113, enacted on December 18, 2015) added a new section 1848(b)(10) of the Act which revises the payment reduction from 25 percent to 5 percent, effective January 1, 2017. Section 502(a)(2)(B) added a new subclause at section 1848(c)(2)(B)(v)(XI) which exempts the reduced expenditures attributable to the revised 5 percent MMPR on the PC of imaging from the PFS budget neutrality provision. We propose to implement these provisions for services furnished on or after January 1, 2017. We refer readers to section VI.C of this proposed rule regarding the necessary adjustment to the proposed PFS conversion factor to account for the mandated exemption from PFS budget neutrality.

We note that the lists of services for the upcoming calendar year that are subject to the MPPR on diagnostic cardiovascular services, diagnostic imaging services, diagnostic ophthalmology services, and therapy services; and the list of procedures that meet the definition of imaging under section 5102(b) of the DRA, and therefore, are subject to the OPPS cap, are displayed in the public use files for the PFS proposed and final rules for each year. The public use files for CY 2017 are available on our Web site under downloads for the CY 2017 PFS proposed rule with comment period at *http://www.cms.gov/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFSFederal-Regulation-Notices.html*.

L. Valuation of Specific Codes

1. Background: Process for Valuing New, Revised, and Potentially Misvalued Codes

Establishing valuations for newly created and revised CPT codes is a routine part of maintaining the PFS. Since inception of the PFS, it has also been a priority to revalue services regularly to make sure that the payment rates reflect the changing trends in the practice of medicine and current prices for inputs used in the PE calculations. Initially, this was accomplished primarily through the 5-year review process, which resulted in revised work RVUs for CY 1997, CY 2002, CY 2007, and CY 2012, and revised PE RVUs in CY 2001, CY 2006, and CY 2011. Under the 5-year review process, revisions in RVUs were proposed and finalized via rulemaking. In addition to the 5-year reviews, beginning with CY 2009, CMS and the RUC have identified a number of potentially misvalued codes each year using various identification screens, as discussed in section II.B.5. of this proposed rule. Historically, when we received RUC recommendations, our process had been to establish interim final RVUs for the potentially misvalued codes, new codes, and any other codes for which there were coding changes in the final rule with comment period for a year. Then, during the 60-day period following the publication of the final rule with comment period, we accepted public comment about those valuations. For services furnished during the calendar year following the publication of interim final rates, we paid for services based upon the interim final values established in the final rule with comment period. In the final rule with comment period for the subsequent year, we considered and responded to public comments received on the interim final values, and typically made any appropriate adjustments and finalized those values.

In the CY 2015 PFS final rule with comment period, we finalized a new process for establishing values for new, revised and potentially misvalued codes. Under the new process, we include proposed values for these services in the proposed rule, rather than establishing them as interim final in the final rule with comment period. Beginning with this CY 2017 proposed rule, the new process will be applicable to all codes, except for new codes that describe truly new services. For CY 2017, we are proposing new values in this proposed rule for the vast majority of new, revised, and potentially misvalued codes for which we received complete RUC recommendations by February 10, 2016. To complete the transition to this new process, for codes where we established interim final values in the CY 2016 PFS final rule with comment period, we reviewed the comments received during the 60-day public comment period following release of the CY 2016 PFS final rule with comment period, and are re-proposing values for those codes in this CY 2017 proposed rule.

We will consider public comments received during the 60-day public comment period for this proposed rule before establishing final values in the final rule with comment period, and adopt interim final values only in the case of wholly new services for which there are no predecessor codes or values and for which we do not receive recommendations in time to propose values. Recommendations regarding any new or revised codes received after February 10th will be considered in the next year's proposed rule (that is, CY 2018 PFS rulemaking).

2. Methodology for Proposing Work RVUs

We conduct a review of each code identified in this section and review the current work RVU (if any), RUC-recommended work RVU, intensity, time to furnish the preservice, intraservice, and postservice activities, as well as other components of the service that contribute to the value. Our review of recommended work RVUs and time inputs generally includes, but is not limited to, a review of information provided by the RUC, HCPAC (Health Care Professionals Advisory Committee), and other public commenters, medical literature, and comparative databases, as well as a comparison with other codes within the PFS, consultation with other physicians and health care professionals within CMS and the federal government, as well as Medicare claims data. We also assess the methodology and data used to develop the recommendations submitted to us by the RUC and other public commenters and the rationale for the recommendations. In the CY 2011 PFS final rule with comment period (75

FR 73328 through 73329), we discussed a variety of methodologies and approaches used to develop work RVUs, including survey data, building blocks, crosswalks to key reference or similar codes, and magnitude estimation (see the CY 2011 PFS final rule with comment period for more information). When referring to a survey, unless otherwise noted, we mean the surveys conducted by specialty societies as part of the formal RUC process. The building block methodology is used to construct, or deconstruct, the work RVU for a CPT code based on component pieces of the code.

Components used in the building block approach may include preservice, intraservice, or postservice time and post-procedure visits. When referring to a bundled CPT code, the building block components could be the CPT codes that make up the bundled code and the inputs associated with those codes. Magnitude estimation refers to a methodology for valuing work that determines the appropriate work RVU for a service by gauging the total amount of work for that service relative to the work for a similar service across the PFS without explicitly valuing the components of that work. In addition to these methodologies, we have frequently utilized an incremental methodology in which we value a code based upon its incremental difference between another code or another family of codes. The statute specifically defines the work component as the resources in time and intensity required in furnishing the service. Also, the published literature on valuing work has recognized the key role of time in overall work. For particular codes, we refine the work RVUs in direct proportion to the changes in the best information regarding the time resources involved in furnishing particular services, either considering the total time or the intraservice time.

Several years ago, to aid in the development of preservice time recommendations for new and revised CPT codes, the RUC created standardized preservice time packages. The packages include preservice evaluation time, preservice positioning time, and preservice scrub, dress and wait time. Currently there are six preservice time packages for services typically furnished in the facility setting, reflecting the different combinations of straightforward or difficult procedure, straightforward or difficult patient, and without or with sedation/anesthesia. Currently, there are three preservice time packages for services typically furnished in the nonfacility setting, reflecting procedures without and with sedation/anesthesia care.

We have developed several standard building block methodologies to value services appropriately when they have common billing patterns. In cases where a service is typically furnished to a beneficiary on the same day as an E/M service, we believe that there is overlap between the two services in some of the activities furnished during the preservice evaluation and postservice time. Our longstanding adjustments have reflected a broad assumption that at least one-third of the work time in both the preservice evaluation and postservice period is duplicative of work furnished during the E/M visit.

Accordingly, in cases where we believe that the RUC has not adequately accounted for the overlapping activities in the recommended work RVU and/or times, we adjust the work RVU and/or times to account for the overlap. The work RVU for a service is the product of the time involved in furnishing the service multiplied by the intensity of the work. Preservice evaluation time and postservice time both have a long-established intensity of work per unit of time (IWPUT) of 0.0224, which means that 1 minute of preservice evaluation or postservice time equates to 0.0224 of a work RVU.

Therefore, in many cases when we remove 2 minutes of preservice time and 2 minutes of postservice time from a procedure to account for the overlap with the same day E/M service, we also remove a work RVU of 0.09 (4 minutes × 0.0224 IWPUT) if we do not believe the overlap in time has already been accounted for in the work RVU. The RUC has recognized this valuation policy and, in many cases, now addresses the overlap in time and work when a service is typically furnished on the same day as an E/M service.

We note that many commenters and stakeholders have expressed concerns with our ongoing adjustment of work RVUs based on changes in the best information we have regarding the time resources involved in furnishing individual services. We are particularly concerned with the RUC's and various specialty societies' objections to our approach given the significance of their recommendations to our process for valuing services and since much of the information we have used to make the adjustments is derived from their survey process. As explained in the CY 2016 PFS final rule with comment period (80 FR 70933), we recognize that adjusting work RVUs for changes is not always a straightforward process, so we apply various methodologies to identify several potential work values for individual codes. However, we want to reiterate that we are statutorily obligated to consider both time and intensity in establishing work RVUs for PFS services.

We have observed that for many codes reviewed by the RUC, final recommended work RVUs appear to be incongruous with recommended assumptions regarding the resource costs in time. This is the case for a significant portion of codes for which we have recently established or proposed work RVUs that are based on refinements to the RUC-recommended values. When we have adjusted work RVUs to account for significant changes in time, we begin by looking at the change in the time in the context of the RUC-recommended work RVU. When the recommended work RVUs do not appear to account for significant changes in time, we employ the different approaches to identify potential values that reconcile the recommended work RVUs with the recommended time values. Many of these methodologies, such as survey data, building blocks, crosswalks to key reference or similar codes, and magnitude estimation have long been used in developing work RVUs under the PFS. In addition to these we sometimes use the relationship between the old time values and the new time values for particular services to identify alternative work RVUs based on changes in time components.

In so doing, rather than ignoring the RUC-recommended value, we are using the recommended values as a starting reference and then applying one of these several methodologies to account for the reductions in time that we believe have not otherwise been reflected in the RUC recommended value. When we believe that such changes in time have already been accounted for in the RUC recommendation, then we do not make such adjustments. Likewise, we do not arbitrarily apply time ratios to current work RVUs to calculate proposed work RVUs. We use the ratios to identify potential work RVUs and consider these work RVUs as potential options relative to the values developed through other options.

We want to make it clear that we are not implying that the decrease in time as reflected in survey values must equate to a one-to-one or linear decrease in newly valued work RVUs. Instead, we believe that since the two components of work are time and intensity that absent an obvious or explicitly stated rationale for why the relative intensity of a given procedure has increased, that significant decreases in time should be reflected in decreases to work RVUs. If the RUC recommendation has appeared to disregard or dismiss the changes in time, without a persuasive explanation of why such a change should not be accounted for in the overall work of the service, then we generally use one of the aforementioned referenced methodologies to identify potential work RVUs, including the methodologies intended to account for the changes in the resources involved in furnishing the procedure.

Several commenters, including the RUC, in general have objected to our use of these methodologies and deemed our actions in adjusting the recommended work RVUs as inappropriate. We received several specific comments regarding this issue in response to the CY 2016 PFS final rule with comment period, those comments are summarized below.

Comment: Several commenters, including the RUC, stated that our methodology for adjusting work RVUs appears to be contrary to the statute.

Response: We disagree with these comments. Since section 1848(c)(1)(A) of the Act explicitly identifies time as one of the two types of resources that encompass the work component of the PFS payment, we do not believe that our use of the aforementioned methodologies to adjust the work RVU to account for the changes in time, which is one of the resources involved, is inconsistent with the statutory requirements related to the maintenance of work RVUs, and we have regularly used these and other methodologies in developing values for PFS services. In selecting which methodological approach will best determine the appropriate value for a service, we consider the current and recommended work and time values, as well as the intensity of the service, all relative to other services. In our review of RUC recommended values, we have observed that the RUC also uses a variety of methodologies to develop work RVUs for individual codes, and subsequently validates the results of these approaches through magnitude estimation or crosswalk to established values for other codes.

Comment: Several commenters, including the RUC, stated that we could not take one element of the services that has changed such as intra-service time, and apply an overall ratio for reduction to the work RVU based on changes to time, as that renders the value no longer resource-based in comparison to the RUC-recommended values.

Response: We disagree with the commenters. We continue to believe that the use of time ratios is one of several reasonable methods for identifying potential work RVUs for particular PFS services, particularly when the alternative values do not account for information that suggests the amount of time involved in furnishing the service has changed significantly. We reiterate that, consistent with the statute, we are required to value the work RVU based on the relative resources involved in furnishing the service, which include time and intensity. When our review of recommended values determines that changes in the resource of time have been unaccounted for in a recommended RVU, then we believe we have the obligation to account for that change in establishing work RVUs since the statute explicitly identifies time as one of the two elements of the work RVUs. We recognize that it would not be appropriate to develop work RVUs solely based on time given that intensity is also an element of work, but in applying the time ratios we are using derived intensity measures based on current work RVUs for individual procedures. Were we to disregard intensity altogether, the work RVUs for all services would be developed based solely on time values and that is definitively not the case. Furthermore, we reiterate that we use time ratios to identify potential work RVUs, and then use other methods (including estimates of work from CMS medical personnel and crosswalks to key reference or similar codes) to validate these RVUs. We also disagree with several commenters' implications that a work RVU developed through such estimation methods is only resource-based through the RUC process.

Comment: Several commenters, including the RUC, stated that our inconsistent use of the time ratio methodology has rendered it ineffective for valuation purposes and that by choosing the starting base work value and/or physician time at random, we are essentially reverse engineering the work value we want under the guise of a standard algorithm.

Response: We do not choose a starting base work value and/or physician time at random as suggested by the commenters. We use the RUC recommended values or the existing values as the base values; essentially, we are taking one of those values and applying adjustments to account for the change in time that based on our analysis of the RUC recommendation, we determine has not been properly accounted for to determine an appropriate work RVU. In circumstances where adjustments to time and the corresponding work RVU are relatively congruent or persuasively explained, our tendency has been to use those values as recommended. Where the RUC recommendations do not account for changes in time, we have made changes to RUC-recommended values to account for the changes in time.

Comment: Commenters, including the RUC, also stated that the use of time ratio methodologies distills the valuation of the service into a basic formula with the only variable being either the new total physician time or the new intra-service physician time, and that these methodologies are based on the incorrect assumption that the per minute physician work intensity established is permanent regardless of when the service was last valued. Other commenters have suggested that previous assumed times are inaccurate.

Response: We agree with commenters that per minute intensity for a given service may change over time. If we believed that the per-minute intensity for a given service were immutable, then a reverse-building block approach to revaluation based on new time data could be appropriate. However, we have not applied such an approach specifically because we agree that the per-minute intensity of work is not necessarily static over time or even necessarily during the course of a procedure. Instead, we utilize time ratios to identify potential values that account for changes in time and compare these values to other PFS services for estimates of overall work. When the values we develop reflect a similar derived intensity, we agree that our values are the result of our assessment that the relative intensity of a given service has remained similar.

Regarding the validity of comparing new times to the old times, we, too, hope that time estimates have improved over many years especially when many years have elapsed since the last time the service in question was valued. However, we also believe that our operating assumption regarding the validity of the pre-existing values as a point of comparison is critical to the integrity of the relative value system as currently constructed. Pre-existing times are a very important element in the allocation of indirect PE RVUs by specialty, and had the previously recommended times been overestimated, the specialties that furnish such services would be benefitting from these times in the allocation of indirect PE RVUs. As long time observers of the RUC process, we also recognize that the material the RUC uses to develop overall work recommendations includes the data from the surveys about time. We have previously stated concerns regarding the validity of much of the RUC survey data. However, we believe additional kinds of concern would be warranted if the RUC itself were operating under the assumption that its pre-existing data were typically inaccurate.

We understand stakeholders' concerns regarding how best to consider changes in time in improving the accuracy of work RVUs and have considered all of the issues raised by commenters. In conjunction with our review of recommended code values for CY 2017, we conducted a preliminary analysis to identify general tendencies in the relationship between changes in time and changes in work RVUs for CY 2014 and CY 2015. We looked at services for which there were no coding changes to simplify the analysis. The intent of this preliminary analysis was to examine commenters' beliefs that CMS is only considering time when making refinements to RUC recommended work values. For CY 2014, we found that in the aggregate, the average difference between the RUC recommended intraservice time and existing intraservice time was −17 percent, but the average difference between the RUC recommended work RVU and existing work RVU was only −4 percent. However, the average difference between the CMS refined work RVU and existing work RVU was −7 percent. For CY 2015, the average difference between the RUC recommended intraservice time and existing intraservice time was −17 percent, but the average difference between the RUC recommended work RVU and existing work RVU was 1 percent, and the average difference between the CMS refined work RVU and existing work RVU was −6 percent. This preliminary analysis demonstrates that we are not making refinements solely in consideration of time, if that were the case, the changes in the work RVU values that we adopted would be comparable to the changes in the time that we adopted, but that is not the case.

We believe that we should account for efficiencies in time when the recommended work RVU does not account for those efficiencies, otherwise relativity across the PFS can be significantly skewed over periods of time. For example, if when a code is first valued, a physician was previously able to do only 5 procedures per day, but due to new technologies, the same physician can now do 10 procedures per day, resource costs in time have empirically been lessened, and we believe that relative reduction in resources involved in furnishing that service should be accounted for in the assignment of work RVUs for that service, since the statute explicitly identifies time as one of the two components of work. Of course, if more resource intensive technology has allowed for the increased efficiency in furnishing the procedure, then the nonfacility PE RVUs for the service should also be adjusted to account for this change. Additionally, we believe it may be that the intensity per minute of the procedure may have changed with the greater efficiency in time. Again, that is why we do not generally reduce work RVUs in strict proportion to changes in time. We understand that intensity is not entirely linear, and that data related to time as obtained in the RUC survey instrument may improve over time, and that the number of survey respondents may improve over time. However, we also understand time as a tangible resource cost in furnishing PFS services, and a cost that by statute, is one of the two kinds of resources to be considered as part of the work RVU.

Therefore, we are interested in receiving comments on whether, within the statutory confines, there are alternative suggestions as to how changes in time should be accounted for when it is evident that the survey data and/or the RUC recommendation regarding the overall work RVU does not reflect significant changes in the resource costs of time for codes describing PFS services. We are also seeking comment on potential alternatives, including the application of the reverse building block methodology, to making the adjustments that would recognize overall estimates of work in the context of changes in the resource of time for particular services.

Table 16 contains a list of codes for which we are proposing work RVUs; this includes all RUC recommendations received by February 10, 2016, and codes for which we established interim final values in the CY 2016 PFS final rule with comment period. When the proposed work RVUs vary from those recommended by the RUC or for which we do not have RUC recommendations, we address those codes in the portions of this section that are dedicated to particular codes. The proposed work RVUs and other payment information for all proposed CY 2017 payable codes are available in Addendum B. Addendum B is available on the CMS Web site under downloads for the CY 2017 PFS proposed rule with comment period at *http://www.cms.gov/physicianfeesched/downloads/*. The proposed time values for all CY 2017 codes are listed in a file called "CY 2017 PFS Proposed Work Time," available on the CMS Web site under downloads for the CY 2017 PFS proposed rule with comment period at *http://www.cms.gov/physicianfeesched/downloads/*.

3. Methodology for Proposing the Direct PE Inputs To Develop PE RVUs

a. Background

On an annual basis, the RUC provides us with recommendations regarding PE inputs for new, revised, and potentially misvalued codes. We review the RUC-recommended direct PE inputs on a code by code basis. Like our review of recommended work RVUs, our review of recommended direct PE inputs generally includes, but is not limited to, a review of information provided by the RUC, HCPAC, and other public commenters, medical literature, and comparative databases, as well as a comparison with other codes within the PFS, consultation with physicians and health care professionals within CMS and the federal government, as well as Medicare claims data. We also assess the methodology and data used to develop the recommendations submitted to us by the RUC and other public commenters and the rationale for the recommendations. When we determine that the RUC recommendations appropriately estimate the direct PE inputs (clinical labor, disposable supplies, and medical equipment) required for the typical service, consistent with the principles of relativity, and reflect our payment policies, we use those direct PE inputs to value a service. If not, we refine the recommended PE inputs to better reflect our estimate of the PE resources required for the service. We also confirm whether CPT codes should have facility and/or nonfacility direct PE inputs and refine the inputs accordingly.

Our review and refinement of RUC-recommended direct PE inputs includes many refinements that are common across codes as well as refinements that are specific to particular services. Table 16 details our proposed refinements of the RUC's direct PE recommendations at the code-specific level. In this proposed rule, we address several refinements that are common across codes, and refinements to particular codes are addressed in the portions of this section that are dedicated to particular codes. We note that for each refinement, we indicate the proposed impact on direct costs for that service. We note that, on average, in any case where the impact on the direct cost for a particular refinement is $0.32 or less, the refinement has no impact on the proposed PE RVUs. This calculation considers both the impact on the direct portion of the PE RVU, as well as the impact on the indirect allocator for the average service. We also note that nearly half of the proposed refinements listed in Table 16 result in changes under the $0.32 threshold and are unlikely to result in a change to the proposed RVUs.

We also note that the proposed direct PE inputs for CY 2017 are displayed in the proposed CY 2017 direct PE input database, available on the CMS Web site under the downloads for the CY 2017 proposed rule at *www.cms.gov/PhysicianFeeSched/*. The inputs displayed there have also been used in developing the proposed CY 2017 PE RVUs as displayed in Addendum B.

b. Common Refinements

(1) Changes in Work Time

Some direct PE inputs are directly affected by revisions in work time. Specifically, changes in the intraservice portions of the work time and changes in the number or level of postoperative visits associated with the global periods result in corresponding changes to direct PE inputs. The direct PE input recommendations generally correspond to the work time values associated with services. We believe that inadvertent discrepancies between work time values and direct PE inputs should be refined or adjusted in the establishment of proposed direct PE inputs to resolve the discrepancies.

(2) Equipment Time

Prior to CY 2010, the RUC did not generally provide CMS with recommendations regarding equipment time inputs. In CY 2010, in the interest of ensuring the greatest possible degree of accuracy in allocating equipment minutes, we requested that the RUC provide equipment times along with the other direct PE recommendations, and we provided the RUC with general guidelines regarding appropriate equipment time inputs. We continue to appreciate the RUC's willingness to provide us with these additional inputs as part of its PE recommendations.

In general, the equipment time inputs correspond to the service period portion of the clinical labor times. We have clarified this principle over several years of rulemaking, indicating that we consider equipment time as the time within the intraservice period when a clinician is using the piece of equipment plus any additional time that the piece of equipment is not available for use for another patient due to its use during the designated procedure. For those services for which we allocate cleaning time to portable equipment items, because the portable equipment does not need to be cleaned in the room where the service is furnished, we do not include that cleaning time for the remaining equipment items, as those items and the room are both available for use for other patients during that time. In addition, when a piece of equipment is typically used during follow-up post- operative visits included in the global period for a service, the equipment time would also reflect that use.

We believe that certain highly technical pieces of equipment and equipment rooms are less likely to be used during all of the preservice or postservice tasks performed by clinical labor staff on the day of the procedure (the clinical labor service period) and are typically available for other patients even when one member of the clinical staff may be occupied with a preservice or postservice task related to the procedure. We also note that we believe these same assumptions would apply to inexpensive equipment items that are used in conjunction with and located in a room with non-portable highly technical equipment items since any items in the room in question would be available if the room is not being occupied by a particular patient. For additional information, we refer readers to our discussion of these issues in the CY 2012 PFS final rule with comment period (76 FR 73182) and the CY 2015 PFS final rule with comment period (79 FR 67639).

(3) Standard Tasks and Minutes for Clinical Labor Tasks

In general, the preservice, intraservice, and postservice clinical labor minutes associated with clinical labor inputs in the direct PE input database reflect the sum of particular tasks described in the information that accompanies the RUC-recommended direct PE inputs, commonly called the "PE worksheets." For most of these described tasks, there are a standardized number of minutes, depending on the type of procedure, its typical setting, its global period, and the other procedures with which it is typically reported. The RUC sometimes recommends a number of minutes either greater than or less than the time typically allotted for certain tasks. In those cases, we review the deviations from the standards and any rationale provided for the deviations. When we do not accept the RUC-recommended exceptions, we refine the proposed direct PE inputs to conform to the standard times for those tasks. In addition, in cases when a service is typically billed with an E/M service, we remove the preservice clinical labor tasks to avoid duplicative inputs and to reflect the resource costs of furnishing the typical service.

In general, clinical labor tasks fall into one of the categories on the PE worksheets. In cases where tasks cannot be attributed to an existing category, the tasks are labeled "other clinical activity." We believe that continual addition of new and distinct clinical labor tasks each time a code is reviewed under the misvalued code initiative is likely to degrade relativity between newly reviewed services and those with already existing inputs. This is because codes more recently reviewed would be more likely to have a greater number of clinical labor tasks as a result of the general tendency to increase the number of clinical labor tasks. To mitigate the potential negative impact of these additions, we review these tasks to determine whether they are fully distinct from existing clinical labor tasks, typically included for other clinically similar services under the PFS, and thoroughly explained in the recommendation. For those tasks that do not meet these criteria, we do not accept these newly recommended clinical labor tasks.

(4) Recommended Items That Are Not Direct PE Inputs

In some cases, the PE worksheets included with the RUC recommendations include items that are not clinical labor, disposable supplies, or medical equipment or that cannot be allocated to individual services or patients. We have addressed these kinds of recommendations in previous rulemaking (78 FR 74242), and we do not use items included in these recommendations as direct PE inputs in the calculation of PE RVUs.

(5) New Supply and Equipment Items

The RUC generally recommends the use of supply and equipment items that already exist in the direct PE input database for new, revised, and potentially misvalued codes. Some recommendations, however, include supply or equipment items that are not currently in the direct PE input database. In these cases, the RUC has historically recommended that a new item be created and has facilitated our pricing of that item by working with the specialty societies to provide us copies of sales invoices. For CY 2017, we received invoices for several new supply and equipment items. Tables 16 and 17 detail the invoices received for new and existing items in the direct PE database. As discussed in section II.A. of this proposed rule with comment period, we encourage stakeholders to review the prices associated with these new and existing items to determine whether these prices appear to be accurate. Where prices appear inaccurate, we encourage stakeholders to provide invoices or other information to improve the accuracy of pricing for these items in the direct PE database during the 60-day public comment period for this proposed rule. We expect that invoices received outside of the public comment period would be submitted by February 10th of the following year for consideration in future rulemaking, similar to our new process for consideration of RUC recommendations.

We remind stakeholders that due to the relativity inherent in the development of RVUs, reductions in existing prices for any items in the direct PE database increase the pool of direct PE RVUs available to all other PFS services. Tables 16 and 17 also include the number of invoices received, as well as the number of nonfacility allowed services for procedures that use these equipment items. We provide the nonfacility allowed services so that stakeholders will note the impact the particular price might have on PE relativity, as well as to identify items that are used frequently, since we believe that stakeholders are more likely to have better pricing information for items used more frequently. A single invoice may not be reflective of typical costs and we encourage stakeholders to provide additional invoices so that we might identify and use accurate prices in the development of PE RVUs.

In some cases, we do not use the price listed on the invoice that accompanies the recommendation because we identify publicly available alternative prices or information that suggests a different price is more accurate. In these cases, we include this in the discussion of these codes. In other cases, we cannot adequately price a newly recommended item due to inadequate information. Sometimes, no supporting information regarding the price of the item has been included in the recommendation. In other cases, the supporting information does not demonstrate that the item has been purchased at the listed price (for example, vendor price quotes instead of paid invoices). In cases where the information provided on the item allows us to identify clinically appropriate proxy items, we might use existing items as proxies for the newly recommended items. In other cases, we have included the item in the direct PE input database without any associated price. Although including the item without an associated price means that the item does not contribute to the calculation of the proposed PE RVU for particular services, it facilitates our ability to incorporate a price once we obtain information and are able to do so.

(6) Service Period Clinical Labor Time in the Facility Setting

Generally speaking, our proposed inputs do not include clinical labor minutes assigned to the service because the cost of clinical labor during the service period for a procedure in the facility setting is not considered a resource cost to the practitioner since Medicare makes separate payment to the facility for these costs. We address proposed code-specific refinements to clinical labor in the individual code sections.

(7) Procedures Subject to the Multiple Procedure Payment Reduction (MPPR) and the OPPS Cap

We note that the public use files for the PFS proposed and final rules for each year display both the services subject to the MPPR lists on diagnostic cardiovascular services, diagnostic imaging services, diagnostic ophthalmology services and therapy services and the list of procedures that meet the definition of imaging under section 1848(b)(4)(B) of the Act, and therefore, are subject to the OPPS cap for the upcoming calendar year. The public use files for CY 2017 are available on the CMS Web site under downloads for the CY 2017 PFS proposed rule with comment period at *http://www.cms.gov/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFSFederal-Regulation-Notices.html.*

4. Specialty-Mix Assumptions for Proposed Malpractice RVUs

The proposed CY 2017 malpractice crosswalk table is displayed in the public use files for the PFS proposed and final rules. The public use files for CY 2017 are available on the CMS Web site under downloads for the CY 2017 PFS proposed rule with comment period at *http://www.cms.gov/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFSFederal-Regulation-Notices.html.* The table lists the CY 2017 HCPCS codes and their respective source codes used to set the proposed CY 2017 MP RVUs where the source code for this calculation deviates from the source code for the utilization otherwise used for purposes of PFS ratesetting. The proposed MP RVUs for all PFS services and the utilization crosswalk used to identify the source codes for all other PFS codes are reflected in Addendum B on the CMS Web site at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/.*

5. Valuation of Specific Codes

a. CY 2017 Proposed Codes That Were Also CY 2016 Proposed Codes

(1) Soft Tissue Localization (CPT Codes 10035 and 10036)

In the CY 2016 PFS final rule with comment period, we established the RUC-recommended work value as interim final for CPT codes 10035 and 10036. We also made standard refinements to remove duplicative clinical labor and utilize standard equipment time formulas for the PACS workstation proxy (ED050).

Comment: A commenter stated that the clinical labor task "Review/read X-ray, lab, and pathology reports" occurs during the preservice period, and it is a separate activity than "Review examination with interpreting MD", which occurs during the service period.

Response: We continue to believe that this clinical labor is duplicative with the clinical labor for Review examination with interpreting MD because we believe that these two descriptors detail the same clinical labor activity taking place, rather than two separate and distinct tasks. We are proposing to maintain our previous refinement to 0 minutes for this clinical labor task for CPT codes 10035 and 10036.

We are also proposing to maintain the interim final work RVUs for CPT codes 10035 and 10036.

(2) Repair Flexor Tendon (CPT Codes 26356, 26357, and 26358)

In the CY 2016 PFS final rule with comment period, we established an interim final work RVU of 9.56 for CPT code 26356 after considering both its similarity in time to CPT code 25607 (Open treatment of distal radial extra-articular fracture) and the recommended reduction in time relative to the current times assumed for this procedure. We established an interim final work RVU of 10.53 for CPT code 26357 based on a direct crosswalk from CPT code 27654 (Repair, secondary, Achilles tendon, with or without graft), as we believed that this work RVU better reflected the changes in time for this procedure. For the last code in the family, we established an interim final work RVU of 12.13 for CPT code 26358, based on the RUC recommended increment of 1.60 work RVUs relative to CPT code 26357.

Comment: We received several comments regarding the interim final work values for this family of codes.

One commenter stated that it was inappropriate to use time ratios to evaluate CPT code 26356 as it was last valued in 1995, noting that there was an anomalous relationship between the current work RVU and the imputed time components in the RUC database. This commenter also pointed out that when the previous time was developed, fabrication of a splint was considered to be part of the intraservice work, while in the current survey instrument, the fabrication of the splint is considered to be part of the postservice work since it is a dressing. This commenter urged CMS to adopt the RUC recommendations. A different commenter agreed that the CMS crosswalk to CPT code 25607 was an appropriate crosswalk for CPT code 26356 and supported the CMS work RVU of 9.56.

Response: We appreciate the support from the commenter. We continue to believe that our crosswalk for this code is an appropriate choice, due to our estimate of overall work between CPT code 26356 and CPT code 25607. We appreciate the commenters' concerns regarding the time ratio methodologies and have responded to these concerns about our methodology in section II.L.2 of this proposed rule. Although we note the commenter's statement about how the service period in which fabrication of a splint takes place may have evolved over time, we do not agree that this task would be responsible for a decrease in intraservice survey time, as the postservice survey time for CPT code 26356 remained unchanged at 30 minutes. If the decrease in intraservice time had been due to the shift of splinting from the intraservice period to the postservice period, then we would have expected to see an increase in the postservice period minutes. However, they remained exactly the same in the physician survey for CPT 26356. As we wrote earlier in this section, we believe in the validity of using pre-existing time values as a point of comparison, and we believe that we should account for efficiencies in time when the recommended work RVU does not account for those efficiencies. After consideration of comments received, we are proposing to maintain CPT code 26356 at its current work RVU of 9.56 for CY 2017.

Comment: Several commenters disagreed with the work RVU for CPT code 26357. One commenter stated that the CMS crosswalk to CPT code 27654 had less total time and resulted in an inappropriately lower intensity. This commenter urged CMS to adopt the RUC-recommended work value. Another commenter stated that a better crosswalk for CPT code 26357 would be CPT code 25608 (Open treatment of distal radial intra-articular fracture or epiphyseal separation), the next code in the same upper extremity family that CMS used for the initial crosswalk. This commenter stated that the CMS crosswalk for CPT code 26357 created a rank order anomaly in terms of intensity within this family, and that the commenter's suggested crosswalk would create two pairs of matched codes, survey CPT codes 26356/26357 with crosswalk CPT codes 25607/25608.

Response: We appreciate the suggested crosswalk from the commenters, and we agree that the choice of the initial CMS crosswalk creates a rank order anomaly within the family in terms of intensity. As a result, after consideration of comments received, we are proposing to instead value CPT code 26357 at the 25th percentile survey work RVU of 11.00 for CY 2017. This valuation corrects the anomalous intensity within the Repair Flexor Tendon family of codes, and preserves the RUC-recommended increment between CPT codes 26356 and 26357.

Comment: The commenters agreed that the RUC-recommended increment of 1.60 was appropriate for the work RVU of CPT code 26358 when added to the work RVU of CPT code 26357. However, commenters stated that this increment of 1.60 should be added to the RUC-recommended work value for CPT code 26357, and not the CMS refined value from the CY 2016 PFS final rule with comment period.

Response: We also continue to believe that the increment of 1.60 is appropriate for the work RVU of CPT code 26358. After consideration of comments received, we are therefore proposing to set the work RVU for this code at 12.60 for CY 2017, based on the increment of 1.60 from CPT code 26357's proposed work RVU of 11.00.

We are proposing to maintain the current direct PE inputs for all three codes.

(3) Esophagogastric Fundoplasty Trans-Oral Approach (CPT Code 43210)

For CY 2016, the CPT Editorial Panel established CPT code 43210 to describe trans-oral esophagogastric fundoplasty. The RUC recommended a work RVU of 9.00 for CPT code 43210. We noted our determination that a work RVU of 7.75, which corresponds to the 25th percentile survey result, more accurately reflects the resources used in furnishing the service associated with CPT code 43210. Therefore, for CY 2016 we established an interim final work RVU of 7.75 for CPT code 43210.

Comment: A few commenters urged CMS to accept the RUC-recommended work RVU of 9.00 for CPT code 43210. The commenters believed that the RUC-recommended value compared well with the key reference service, CPT code 43276 (Endoscopic retrograde cholangiopancreatography (ERCP); with removal and exchange of stent(s), biliary or pancreatic duct, including pre- and post-dilation and guide wire passage, when performed, including sphincterotomy, when performed, each stent exchanged), which has a work RVU of 8.94 and an intraservice time of 60 minutes. Commenters believed that due to similar intra-service times and intensities, that CPT code 43210 should be valued nearly identically to CPT code 43276. Some commenters also stated that to maintain relativity within the upper GI code families, CPT code 43210 should not have a lower work RVU than CPT code 43276, especially since the majority of survey participants indicated that CPT code 43210 is "somewhat more" complex than CPT code 43276. Additionally, one commenter noted that an EGD (Esophagogastroduodenoscopy) is used twice during this service, before and after fundoplication. They stated that because this is a multi-stage procedure, other EGD codes are not comparable. The commenter also pointed out that this technology has a small number of users and urged us to accept the RUC-recommended work RVU of 9.00 until there is increased volume and then reassess in 2 years. Commenters also requested refinement panel consideration for this service.

Response: Per the commenters' request, we referred this code to the CY 2016 multi-specialty refinement panel for further review. The result of the panel was a recommendation that we accept the RUC-recommended value of 9.00 work RVUs. However, since there are four ERCP codes with 60 minutes of intraservice time, three of which have work RVUs of less than 7.00 and only one of the four codes has a work RVU higher than 7.75 RVUs (8.94), based on our estimate of overall work for this service, we continue to believe that the 25th percentile of the survey most accurately reflects the relative resource costs associated with CPT code 43210. Therefore, for CY 2017 we are proposing a work RVU of 7.75 for CPT code 43210.

(4) Percutaneous Biliary Procedures Bundling (CPT Codes 47531, 47532, 47533, 47534, 47535, 47536, 47537, 47538, 47539, 47540, 47541, 47542, 47543, and 47544)

These codes were revalued with new recommendations at the October 2015

RUC meeting; we will discuss the CY 2016 interim final comments alongside the new recommendations. Please see section II.L for a discussion of the CY 2017 proposed code values.

(5) Percutaneous Image Guided Sclerotherapy (CPT Code 49185)

For CY 2016, we established an interim final work RVU of 2.35 for CPT code 49185 based on a crosswalk from CPT code 62305 (Myelography via lumbar injection, including radiological supervision and interpretation; 2 or more regions (*e.g.*, lumbar/thoracic, cervical/thoracic, lumbar/cervical, lumbar/thoracic/cervical)); which we believed accurately reflected the time and intensity involved in furnishing CPT code 49185. We also requested stakeholder input on the price of supply item SH062 (sclerosing solution) as the volume of the solution in this procedure (300 mL) is much higher than other CPT codes utilizing SH062 (between 1 and 10 mL).

Comment: Commenters disagreed with our proposed crosswalk of CPT code 49185 from CPT code 62305. Commenters believed that the RUC-recommended crosswalk from CPT code 31622 (Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with cell washing, when performed (separate procedure)) was a more appropriate comparison due to similarity in service. Commenters requested that CPT code 49185 be referred to the refinement panel.

Response: The requests did not meet the requirements related to new clinical information for referral to the refinement panel. After review of the comments, we continue to believe that a crosswalk of CPT code 49185 from the value for CPT code 62305 is most appropriate due to similarities in overall work. Therefore, we are proposing a work RVU of 2.35 for CPT code 49185 for CY 2017 and seek additional rationale for why a different work RVU or crosswalk would more accurately reflect the resources involved in furnishing this service.

Comment: A commenter stated that the procedure described by CPT code 49185 involved a separate clinical labor staff type. Due to the inclusion of this additional individual, the L037D clinical labor and additional gloves were appropriate to include in the procedure.

Response: The commenter did not provide any evidence for this claim. We continue to believe that this additional use of clinical staff would not be typical for CPT code 49185. This procedure does not involve moderate sedation, and therefore, we do not believe that there would be a typical need for a third staff member. As a result, we are proposing to maintain our direct PE refinements from the CY 2016 PFS final rule with comment period.

Additionally, we did not receive any information regarding SH062 that supports maintaining an input of 300 mL, and as noted above, this level far exceeds the volume associated with other CPT codes; therefore, we are proposing to refine the direct practice expense inputs for SH062 from 300 mL to 10 mL, which is the highest level associated with other CPT codes utilizing SH062.

(6) Genitourinary Procedures (CPT Codes 50606, 50705, and 50706)

In the CY 2016 PFS final rule with comment period, we established as interim final the RUC-recommended work RVUs for all three codes. We did not receive any comments on the work values for these codes, and we are proposing to maintain all three at their current work RVUs.

The RUC recommended the inclusion of "room, angiography" (EL011) for this family of codes. As we discussed in the CY 2016 PFS final rule with comment period, we did not believe that an angiography room would be used in the typical case for these procedures, and we therefore replaced the recommended equipment item "room, angiography" with equipment item "room, radiographic-fluoroscopic" (EL014) for all three codes on an interim final basis. We also stated our belief that since the predecessor procedure codes generally did not include an angiography room and we did not have a reason to believe that the procedure would have shifted to an angiography room in the course of this coding change, we did not believe that the use of an angiography room would be typical for these procedures.

Comment: Several commenters disagreed with the CMS substitution of the fluoroscopic room in place of the angiography room. The commenters stated that all three of these procedures were previously reported using CPT code 53899 (Unlisted procedure, urinary system) which does not have any PE inputs, and the RUC recommendations included as a reference CPT code 50387 (Removal and replacement of externally accessible transnephric ureteral stent), which includes an angiography room. The commenters suggested that CPT code 50387 was an example of a predecessor code that included the use of an angiography room, along with other codes that are being bundled together to create the new Genitourinary codes.

Response: We do not agree with the commenter's implication that because CPT code 50387 was an appropriate reference code for use in valuation, that it necessarily would have previously been used to describe services that are now reported under CPT codes 50606, 50705, or 50706. Our perspective is consistent with the RUC-recommended utilization crosswalk for the three new codes, which did not suggest that the services were previously reported using 50706. We do not believe that use of one particular code for reference in developing values for another necessarily means that the all of the same equipment would be used for both services.

We do not believe that these codes describe the same clinical work either. CPT code 50387 is for the "Removal and replacement of externally accessible transnephric ureteral stent" while CPT code 50606 describes an "Endoluminal biopsy of ureter and/or renal pelvis", CPT code 50705 refers to "Ureteral embolization or occlusion", and CPT code 50706 details "Balloon dilation, ureteral stricture." Additionally, the codes do not have the same global periods, which makes comparisons between CPT code 50387 and CPT codes 506060, 50705, and 50706 even more difficult. We note that despite the commenter's claim that CPT code 50387 was provided as a reference for these procedures, 50387 is not in fact listed as a reference for any of these three codes, or mentioned at all in the codes' respective summary of recommendations. However, we acknowledge that among the procedures that are provided as references, many of them include the use of an angiography room, such as CPT code 36227 (Selective catheter placement, external carotid artery) and CPT code 37233 (Revascularization, endovascular, open or percutaneous, tibial/peroneal artery, unilateral, each additional vessel). Therefore, we agree that the use of the angiography room in these procedures, or at least some of its component parts, may be warranted.

Comment: A commenter stated that the substitution of the fluoroscopic room for the angiography room was clinically unjustified. The commenter stated that the angiography room was needed for these procedures to carry out 3-axis rotational imaging (so as to avoid rolling the patient), ensure sterility, and avoid unacceptable radiation exposure to physicians, their staff, and their patients. The commenter indicated that the only piece of equipment listed in the angiography room that would not be typically utilized for these procedures is the Provis Injector. All of the other items are used for these Genitourinary procedures. The commenter urged CMS to restore the angiography room to these procedures.

Response: We agree that it is important to provide equipment that is medically reasonable and necessary. Our concern with the use of the angiography room for these codes is that we do not believe all of the equipment would be typically necessary to furnish the procedure. For example, the commenter agreed that the Provis Injector would not be required for these Genitourinary codes. Therefore, we are proposing to remove the angiography room from these three procedures and add in its place the component parts that make up the room. Table 16 details these components:

TABLE 16—ANGIOGRAPHY ROOM (EL011) COMPONENTS

100 KW at 100 kV (DIN6822) generator
C-arm single plane system, ceiling mounted, integrated multispace
T motorized rotation, multiple operating modes
real-time digital imaging
40 cm image intensifier at 40/28/20/14cm
30 × 38 image intensifier dynamic flat panel detector
floor-mounted patient table with floating tabletop designed for angiographic exams and interventions (with peistepping for image intensifiers 13in+)
18 in TFT monitor
network interface (DICOM)
Careposition: Radiation free positioning of collimators
Carewatch: Acquisition and monitoring of configurable dose area product
Carefilter: Cu-prefiltration
DICOM HIS/RIS
Control room interface
Injector, Provis
Shields, lower body and mavig
Leonardo software
Fujitsu-Siemens high performance computers
Color monitors
Singo modules for dynamic replay and full format images
Prepared for internal networking and Siemens remote servicing, both hardware and software

We will include all of the above components except the Provis Injector, as commenters have indicated that its use would not be typical for these procedures. We welcome additional comment regarding if these or other components are typically used in these Genitourinary procedures. We currently lack pricing information for these components; we are therefore proposing to include each of these components in the direct PE input database at a price of $0.00 and we are soliciting invoices from the public for their costs so that we may be able to price these items for use in developing final PE RVUs for CY 2017

We also note that we believe that this issue illustrates a potentially broad problem with our use of equipment "rooms" in the direct PE input database. For most services, we only include equipment items that are used and unavailable for other uses due to their use during the services described by a particular code. However, for items included in equipment "rooms," we allocate costs regardless of whether the individual items that comprise the room are actually used in the particular service.

To maintain relativity among different kinds of procedures, we are interested in obtaining more information specifying the exact resources used in furnishing services described by different codes. We hope to address this subject in greater detail in future rulemaking.

(7) Laparoscopic Radical Prostatectomy (CPT code 55866)

In the CY 2016 PFS final rule with comment period, we established an interim final work RVU of 21.36 for CPT code 55866 based on a direct crosswalk to CPT code 55840 (Prostatectomy, retropubic radical, with or without nerve sparing). We stated that we believed these codes were medically similar procedures with nearly identical time values, and we did not believe that the difference in intensity between CPT code 55840 and CPT code 55866 was significant enough to warrant the RUC-recommended difference of 5.50 work RVUs. We also compared CPT code 55866 to the work RVU of 25.18 for CPT code 55845, and stated our belief that, in general, a laparoscopic procedure would not require greater resources than an open procedure.

Comment: Several commenters disagreed with the statement that a laparoscopic procedure, such as CPT code 55866, would generally require fewer resources than an open procedure, such as CPT code 55840. Commenters stated that developing the skill necessary to perform a minimally invasive laparoscopic surgery requires a greater degree of experience and specialized training than that required to perform an open prostatectomy. Commenters indicated that this level of practitioner skill should be reflected in the work RVU for the procedure, as intensity is based in part upon skill, mental effort, and psychological stress.

Response: We agree with the commenters that skill and technique as well as mental effort and psychological stress on the part of the practitioner contribute to the overall intensity of the furnishing a given service, and therefore, are one of the two components in determining code-level work RVUs. However, we do not believe that relative increases in requisite skill or technique can be considered alone. Although the development of new technology (such as robotic assistance) may create a greater burden of knowledge on the part of the practitioner, it can also make procedures faster, safer, and easier to perform. This means that there may be reductions in time for such a procedure (which is the other component of the work RVU), but also that the mental effort and psychological stress for a given procedure may be mitigated by the improvements in safety. Therefore, we do not agree that a newer procedure that includes additional technology and requires greater training would inherently be valued at a higher rate than an older and potentially more invasive procedure.

Comment: A commenter stated that CPT code 55866 describes two very different procedures in one code. The descriptor for the code states "includes robotic assistance when performed", and the procedure is performed differently depending on whether or not the robotic assistance is included. The commenter indicated that the vast majority of radical prostatectomies are performed with the robot, and although the outcomes are the same in both cases, the procedures are completely different.

Response: We agree with the commenter that the descriptor includes the possibility for confusion, especially on the part of the survey respondents. Valuing this code based on the typical case is difficult when the procedure differs depending on the inclusion or exclusion of robotic assistance. We would recommend that valuation might be improved if the CPT Editorial Panel were to consider further revisions to this code to describe the two cases of laparoscopic radical prostatectomy: With and without robotic assistance.

Comment: One commenter stated that the application of the phase-in transition for facility-only codes like CPT code 55866 would have a particularly egregious impact in the second year of the transition. The commenter urged CMS to ensure that its implementation of the phase-in transition does not undermine the protections created by the statute.

Response: Please see Sections II.G and II.H or a discussion of the phase-in transition and its implementation in its second year.

Comment: Several commenters requested that CMS refer CPT code 55866 to the refinement panel for review. At the refinement panel, the presenters brought up new evidence in the form of a study published in 2016 describing discharge data for radical laparoscopic prostatectomies. The presenters stated that there were many more people included in this study as opposed to the 30 respondents in the survey data, and that on average the robotic procedure took 90 minutes longer than the open procedure. The additional time needed to perform the procedure, as indicated by this new study's results, was presented as a new rationale as to why CMS should accept the RUC-recommended work RVU.

Response: CPT code 55866 was referred to the CY 2016 Multi-Specialty Refinement Panel per the request of commenters. The outcome of the refinement panel was a median work RVU of 26.80, the same value as the RUC recommended in the previous rulemaking cycle. After consideration of the comments and the results of the refinement panel, we are proposing for CY 2017 to maintain the interim final work RVU of 21.36 for CPT code 55866. We are interested in the results of the study mentioned at the refinement panel, and we will consider incorporating this data into the valuation of this code, including, if appropriate, adjustments to the work times used in PFS ratesetting. We are also seeking that the study be submitted through the public comment process so that we can allow it proper consideration along with other information submitted by the public, rather than using the results of a single study to propose valuations. We are also curious about the time values regarding the duration of CPT code 55866. One of the members of the refinement panel stated that on average the robotic procedure took 90 minutes longer than the open procedure. This is not what was indicated by the survey data from the RUC recommendations, which had the two procedures valued at virtually identical times (same intraservice time, 6 minutes difference total time). We are therefore seeking comment on whether the times included in this study are more accurate than the time reflected in the RUC surveys.

(8) Intracranial Endovascular Intervention (CPT codes 61645, 61650, and 61651)

For CY 2016, we established interim final work RVUs of 15.00 for CPT code 61645, 10.00 for CPT code 61650 and 4.25 for CPT code 61651. The RUC-recommended values for CPT codes 61645, 61650 and 61651 were 17.00, 12.00 and 5.50, respectively. We valued CPT code 61645 by applying the ratio between the RUC-recommended reference code's, CPT 37231 (revascularization, endovascular, open or percutaneous, tibial, peroneal artery, unilateral, initial vessel; with transluminal stent placement(s) and atherectomy, includes angioplasty within the same vessel, when performed), work and time to CPT code 61645. We valued CPT code 61650 based on a crosswalk to CPT code 37221 (revascularization, endovascular, open or percutaneous, iliac artery, unilateral, initial vessel; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed), due to similar intensity and intraservice time. We valued CPT code 61651 based on a crosswalk to CPT code 37223 (revascularization, endovascular, open or percutaneous, iliac artery, each additional ipsilateral iliac vessel; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed (list separately in addition to the code for primary procedure, due to similar intraservice time and intensity.

Both CPT codes 61645 and 61650 included postservice work time associated with CPT code 99233 (Subsequent hospital care, per day, for the evaluation and management of a patient, which requires at least 2 of these 3 key components: A detailed interval history; A detailed examination; Medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the patient is unstable or has developed a significant complication or a significant new problem. Typically, 35 minutes are spent at the bedside and on the patient's hospital floor or unit). In the CY 2016 PFS final rule with comment period, we stated that we believe that for the typical patient, these services would be considered hospital outpatient services, not inpatient services. As a result the intraservice time of the hospital observation care service was valued in the immediate postservice time. We refined the work time for CPT code 61645 by removing 55 minutes of work time associated with CPT code 99233, and added 30 minutes of time from CPT code 99233 to the immediate postservice. Therefore the total time for CPT code 61645 was reduced to 241 minutes and the immediate postservice time increased to 83 minutes. We also removed the inpatient visit from CPT code 61650, which reduced the total time to 206 minutes and increased the postservice time to 75 minutes.

Comment: Commenters disagreed with our categorization of these codes as outpatient only, and therefore, subject to the 23-hour outpatient policy. Commenters stated that according to Medicare claims data, the predecessor codes were performed primarily on an inpatient basis. Additionally, commenters pointed out that the new codes would typically be performed on acute stroke patients. Commenters also said as the new codes are inpatient-only, the CMS reductions in work and time based on the assumption of outpatient status are flawed; as a result, commenters suggested we accept the RUC-recommended values. Commenters also requested that these codes be referred to the refinement panel.

Response: We valued CPT codes 61645, 61650, and 61651 based on comparisons to reference CPT codes 37231, 37221, and 37223, respectively. We continue to believe that these codes are appropriate comparisons based on intensity and intra-service time because no persuasive information was presented at the refinement panel that indicated that these comparisons are not appropriate. Therefore we are proposing an RVU of 15.00 for CPT code 61645, 10.00 for CPT code 61650, and 4.25 for CPT code 61651. We are also proposing time inputs based on our refinements of the RUC recommendations, including removing the time associated with hospital inpatient visit CPT code 99233 from the intraservice work time, and adding 30 minutes to the immediate postservice time for both CPT codes 61645 and 61650.

We are also seeking comment on the inclusion of post-operative visits in a 0-day global. Both CPT codes 61645 are 0-day global codes, and the refinements described above reflect changes to more appropriate value these codes as 0-day codes. We do not believe that 0-day globals codes should include post-operative visits; rather, if global codes require post-operative visits, they are more appropriately assigned 10- or 90-day global periods based on our current criteria. Our policy has been to remove the visit from the post-operative period and the associated minutes from the total time while adding 30 minutes to the immediate postservice period without necessarily making an adjustment to the work RVU (see the CY 2010 PFS proposed rule, 74 FR 33557; also see the CY 2011 PFS proposed rule, 75 FR 40072).

(9) Paravertebral Block Injection (CPT codes 64461, 64462, and 64463)

In CY 2015, the CPT Editorial Panel created three new codes to describe paravertebral block injections at single or multiple levels, as well as for continuous infusion for the administration of local anesthetic for post-operative pain control and thoracic and abdominal wall analgesia. For the CY 2016 PFS final rule with comment period, we established the RUC-recommended work RVUs, 1.75 and 1.10, as interim final for CPT codes 64461 and 64462, respectively.

For CPT code 64463, we utilized a direct crosswalk from three other injection codes (CPT codes 64416 (Injection, anesthetic agent; brachial plexus, continuous infusion by catheter (including catheter placement), 64446 (Injection, anesthetic agent; sciatic nerve, continuous infusion by catheter (including catheter placement), and 64449 (Injection, anesthetic agent; lumbar plexus, posterior approach, continuous infusion by catheter (including catheter placement)) which all had a work RVU of 1.81 as we believed this crosswalk more accurately reflected the work involved in furnishing this service.

Comment: The RUC stated that CPT code 64463 is more comparable to CPT code 64483 (Injection(s), anesthetic agent and/or steroid, transforaminal epidural, with imaging guidance (fluoroscopy or CT); lumbar or sacral, single), which has a work RVU of 1.90 and requires the same physician work and time to perform. The RUC recommended we accept the 25th percentile survey work RVU of 1.90. Another commenter stated that our value for CPT code 64463 was inappropriate since imaging guidance is not part of our comparison codes. The commenter advocated for us to accept the survey respondent's selection of CPT code 64483 as the most appropriate comparison code and assign a work RVU of 1.90.

Response: After reviewing and considering the comments, we continue to believe that CPT codes 64416, 64446, and 64449, all of which have 20 minutes of intraservice time, are better crosswalks to CPT code 64463, which also has 20 minutes of intraservice time and a similar total time. In contrast, the crosswalk code recommended by commenters, CPT 64483, only has 15 minutes of intraservice time. Therefore, we are proposing a work RVU of 1.81 for CPT code 64463 for CY 2017.

(10) Implantation of Neuroelectrodes (CPT codes 64553 and 64555)

The RUC identified CPT codes 64553 and 64555 as a site of service anomaly during the CY 2016 PFS rulemaking cycle. In the Medicare claims data, these services were typically reported in the nonfacility setting, yet the survey data was predicated on a facility-based procedure. We agreed with the RUC that these two codes should be referred to the CPT Editorial Panel to better define the services, in particular to investigate the possibility of establishing one code to describe temporary or testing implantation and another code to describe permanent implantation. We maintained the CY 2015 work RVUs and direct PE inputs for these two codes on an interim basis until receiving updated recommendations from CPT and the RUC.

Comment: A commenter requested that CMS allow practitioners to bill the MACs separately for a percutaneous electrode kit (SA022) for CPT code 64555. The commenter stated that without allowing for a separate payment for the percutaneous electrode kit, the payment for the procedure would be insufficient to cover the physician's costs.

Response: We agree that CPT codes 64553 and 64555 as currently constructed are potentially misvalued codes, which is why we are maintaining the CY 2015 work RVUs and direct PE inputs on an interim basis. We believe that the disposable supplies furnished incident to the procedure are paid through the nonfacility PE RVUs. The percutaneous electrode kit (SA022) was not previously included in the direct PE inputs for either of these two services, and since we are proposing to maintain current direct PE inputs pending additional recommendations, we do not agree that disposable supplies should be separately payable. We are proposing to maintain the interim final work RVUs and direct PE inputs for these two codes, and we look forward to reviewing recommendations regarding these procedures again for future rulemaking.

Additionally, we were alerted to a discrepancy regarding the times for these codes in the CY 2016 work time file. Our proposed CY 2017 work time file addresses this discrepancy by reflecting the RUC recommended times of 155 minutes for CPT code 64553 and 140 minutes for CPT code 64555.

(11) Ocular Reconstruction Transplant (CPT code 65780)

In CY 2015, the RUC identified CPT code 65780 as potentially misvalued through a misvalued code screen for 90-day global services that included more than 6 office visits. The RUC recommended a direct work RVU crosswalk from CPT code 27829 (Open treatment of distal tibiofibular joint (syndesmosis) disruption, includes internal fixation, when performed). After examining comparable codes, we determined the RUC-recommended work RVU of 8.80 for CPT code 65780 would likely overstate the work involved in the procedure given the change in intraservice and total times compared to the previous values. We believed that the ratio of the total times (230/316) applied to the work RVU (10.73) more accurately reflected the work involved in this procedure. Therefore, we established an interim final work RVU of 7.81 for CPT code 65780.

Comment: The RUC and other commenters disagreed with our interim final values based on objections to our use of time ratios in developing work RVUs for PFS services.

Response: We appreciate the commenters' concerns and have responded to these concerns about our methodology in section II.L of this proposed rule. After review of the comments, we continue to consider the work RVU of 7.81 to accurately represent the work involved in CPT code 65780. We believe this service is similar in overall intensity to CPT code 27766 (Open treatment of medial malleolus fracture, includes internal fixation, when performed) that has a work RVU of 7.89 and a total time that more closely approximates that of CPT code 65780. Therefore, we are proposing a work RVU of 7.81 for CPT code 65780 for CY 2017.

(12) Trabeculoplasty by Laser Surgery (CPT code 65855)

In CY 2015, the RUC identified CPT code 65855 as potentially misvalued through the review of 10-day global services with more than 1.5 postoperative visits. The RUC noted that the code was changed from a 90-day to a 10-day global period when it was last valued in 2000. However, the descriptor was not updated to reflect that change. CPT code 65855 describes multiple laser applications to the trabecular meshwork through a contact lens to reduce intraocular pressure. The current practice is to perform only one treatment session during a 10-day period and then wait for the effect on the intraocular pressure. The descriptor for CPT code 65855 has been revised and removes the language ''1 or more sessions'' to clarify this change in practice.

The RUC recommended a work RVU of 3.00 for CPT code 65855. While the RUC-recommended value represents a reduction from the CY 2015 work RVU of 3.99, we stated that significant reductions in the intraservice time, the total time, and the change in the office visits represent a more significant change in the work resources involved in furnishing the typical service. The intraservice and total times were decreased by approximately 33 percent while the elimination of two post-operative visits (CPT code 99212) alone would reduce the overall work RVU by at least 24 percent under the reverse building block method. However, the RUC-recommended work RVU only represents a 25 percent reduction relative to the previous value. To identify potential work RVUs for this service, we calculated an intraservice time ratio between the CY 2015 intraservice time, 15 minutes, and the RUC-recommended intraservice time, 10 minutes, and applied this ratio to the current work RVU of 3.99 to arrive at a work RVU of 2.66 for CPT code 65855, which we established as interim final for CY 2016.

Comment: A few commenters, including the RUC, provided explanations as to how the RUC recommendation had already accounted for the reduction in physician intra-service time and post-operative visits. Some commenters disagreed with CMS' interim final values based on objections to CMS' use of time ratios in developing work RVUs for PFS services.

Response: We appreciate the commenters' concerns regarding the time ratio methodologies and have responded to these concerns about our methodology in section II.H.2 of this proposed rule. After considering the explanations provided by commenters through public comments describing the RUC's methodologies in more detail, we agree that the proposed value did not accurately reflect the physician work involved in furnishing the service. Therefore, for CY 2017 we are proposing the RUC-recommended work RVU value of 3.00 for CPT code 65855.

(13) Glaucoma Surgery (CPT codes 66170 and 66172)

The RUC identified CPT codes 66170 and 66172 as potentially misvalued through a screen for 90-day global codes that included more than 6 office visits). We believed the RUC-recommended work RVU of 13.94 for CPT code 66170 did not accurately account for the reductions in time. Specifically, the survey results indicated reductions of 25 percent in intraservice time and 28 percent in total time. These reductions suggested that the RUC-recommended work RVU for CPT code 66170 overstated the work involved in furnishing the service, since the recommended value only represented a reduction of approximately seven percent. We believed that applying the intraservice time ratio, the ratio between the CY 2015 intraservice time, 60 minutes, and the RUC-recommended intraservice time, 45 minutes, applied to the current work RVU, 15.02, resulted in a more appropriate work RVU. Therefore, for CY 2016, we established an interim final work RVU of 11.27 for CPT code 66170.

For CPT code 66172, the RUC recommended a work RVU of 14.81. After comparing the RUC-recommended work RVU for this code to the work RVU for similar codes (for example, CPT code 44900 (Incision and drainage of appendiceal abscess, open) and CPT code 52647 (Laser coagulation of prostate, including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, and internal urethrotomy are included if performed))), we believed the RUC-recommended work RVU of 14.81 overstated the work involved in this procedure. For the same reasons and following the same valuation methodology utilized above, we applied the intraservice time ratio between the CY 2015 intraservice time and the survey intraservice time, 60/90, to the CY 2015 work RVU of 18.86. This resulted in a work RVU of 12.57 for CPT code 66172. Therefore, for CY 2016, we established an interim final work RVU of 12.57 for CPT code 66172.

Comment: Several commenters, including the RUC, disagreed with our interim final values based on objections to our use of time ratios in developing work RVUs for PFS services. Commenters also requested CMS refer CPT codes 66170 and 66172 to the refinement panel.

Response: We appreciate the commenters' concerns regarding the time ratio methodologies and have responded to these concerns in section II.H.2 of this proposed rule. CPT codes 66170 and 66172 were referred to the CY 2016 multi-specialty refinement panel per commenters' request. The outcome of the refinement panel was a median of 13.94 RVUs for CPT code 66170 and 14.84 RVUs for CPT code 66172. Due to the new information presented to the refinement panel regarding the level of intensity required to perform millimeter incisions in the eye, we agree with the assessment of the refinement panel and therefore, for CY 2017 we are proposing a work RVU of 13.94 for CPT code 66170 and 14.84 for CPT code 66172.

(14) Retinal Detachment Repair (CPT codes 67107, 67108, 67110, and 67113)

CPT codes 67107, 67108, 67110 and 67113 were identified as potentially misvalued through a screen for 90-day global post-operative visits. The RUC recommended a work RVU of 16.00 for CPT code 67107, which corresponded to the 25th percentile of the survey. While the RUC recommendation represented a five percent reduction from the current work RVU of 16.71, we believed the RUC recommendation still overvalued the service given the 15 percent reduction in intraservice time and 25 percent reduction in total time. We used the intraservice time ratio between the existing and new time values to identify an interim final work RVU of 14.06. We believed this value accurately reflected the work involved in this service and was comparable to other codes that have the same global period and similar intraservice time and total time. For CY 2016, we established an interim final work RVU of 14.06 for CPT code 67107.

For CPT code 67108, the RUC recommended a work RVU of 17.13 based on the 25th percentile of the survey, which reflected a 25 percent reduction from the current work RVU. The survey results reflected a 53 percent reduction in intraservice time and a 42 percent reduction in total time. We believe the RUC-recommended work RVU overestimated the work, given the significant reductions in intraservice time and total time and does not maintain relativity among the codes in this family. To determine the appropriate value for this code and maintain relativity within the family, we preserved the 1.13 work RVU increment recommended by the RUC between this code and CPT code 67107 and applied that increment to the interim final work RVU of 14.06 for CPT code 67107. Therefore, we established an interim final work RVU of 15.19 for CPT code 67108.

For CPT code 67110, the RUC recommended maintaining the current work RVU of 10.25. To maintain appropriate relativity with the work RVUs established for the other services within this family, we used the RUC-recommended −5.75 RVU differential between CPT code 67107 and CPT code 67110 to establish the CY 2016 interim final work RVU of 8.31 for CPT code 67110. For CPT code 67113, the RUC recommended and we established an interim final work RVU of 19.00 based on the 25th percentile of the survey.

Comment: Several commenters, including the RUC, disagreed with our interim final values based on objections to our use of time ratios in developing work RVUs for PFS services. Some commenters also stated that by using some RUC-recommended increments and rejecting others, we have not only established inconsistencies within the family of codes, but potentially opened up anomalies across a wide range of services. The RUC also expressed disagreement with using the recommended work RVU increments without using the recommended work RVU. Some commenters also stated the new IWPUT values for these three services are inappropriately low and pointed to the derived per minute intensity of 0.064 for CPT code 67110 as particularly problematic.

Response: We appreciate the commenters' concerns regarding the time ratio methodologies and have responded to these concerns in section II.H.2 of this proposed rule. We disagree with the statement about inconsistencies as the codes in this family are valued relative to one another based on the times and level of physician work required for each code. Also, we generally do not agree that a low IWPUT itself indicates overall misvaluation as the validity of the IWPUT as a measure of intensity depends on the accuracy of the assumptions regarding the number, level, and work RVUs attributable to visits for services in the post-operative global period for individual services. For example, a service with an unrealistic number or level of post-operative visits may have a very low derived intensity for the intra-service time.

CPT codes 67107, 67108, and 67110 were referred to the CY 2016 multi-specialty refinement panel per commenters' request. The outcome of the refinement panel was a median of 16.00, 17.13, and 10.25 work RVUs; respectively. After consideration of the comments and the results of the refinement panel, we are proposing a work RVU of 16.00, 17.13, and 10.25 for CPT codes 67107, 67108, and 66110, respectively, for CY 2017.

(15) Fetal MRI (CPT Codes 74712 and 74713)

For CY 2016, we established the RUC-recommended work RVU of 3.00 as interim final for CPT code 74712. We established an interim final work RVU of 1.78 for CPT code 74713 based on a refinement of the RUC-recommended work RVU of 1.85 using the ratio of work to time for both codes. This proposed value also corresponds to the 25th percentile survey result.

Comment: Commenters stated that the work RVU of 1.78 for CPT code 74713 did not reflect the higher intensity inherent in the procedure's typical patient. The commenter explained that the typical patient is pregnant with twins and has a higher likelihood of complications related to congenital anomalies, as well as of ischemic brain injury with twin gestations. The commenter further stated that twin gestations are more difficult to image. Commenters requested that CPT code 74713 be referred to the multispecialty refinement panel.

Response: CPT code 74713 was referred to the CY 2016 multispecialty refinement panel. After considering the comments and the results of the refinement panel, we agree with commenters that an RVU of 1.78 underestimates the work for CPT code 74713. Therefore, we propose a work RVU of 1.85 for the service for CY 2017.

(16) Interstitial Radiation Source Codes (CPT Codes 77778 and 77790)

In CY 2016 PFS final rule with comment period, we established an interim final value for CPT code 77790 without a work RVU, consistent with the RUC's recommendation. We did not use the RUC-recommended work RVU to establish the interim final values for CPT code 77778. We stated that the specialty society survey included a work time that was significantly higher than the RUC-recommended work time without a commensurate change in RVU. For CY 2016, we established the 25th percentile work RVU survey result of 8.00 as interim final for CPT code 77778.

Comment: Commenters agreed that the preservice survey times and the RUC-recommended survey times were inconsistent and explained that this inconsistency resulted from the RUC's use of preservice packages in developing recommendations. In addition, commenters stated that because the work associated with CPT code 77790 (including pre-time supervision, handling, and loading of radiation seeds into needles) was bundled into CPT code 77778, that the additional work should be reflected in the RVU for CPT code 77778. Commenters encouraged us to accept the RUC-recommended work RVU of 8.78 and requested that CPT code 77778 be referred to the refinement panel.

Response: We did not refer CPT code 77778 to the CY 2016 multispecialty refinement panel because commenters did not provide new clinical information. We continue to believe that, based on the reduction in total work time, an RVU of 8.00 accurately reflects the work involved in furnishing CPT code 77778. Therefore for CY 2017, we are proposing a work RVU of 8.00 for CPT code 77778 and 0 work RVUs for CPT code 77790. We are also seeking comment on whether we should use time values based on preservice packages if the recommended work value is based on time values that are significantly different than those ultimately recommended.

(17) Colon Transit Imaging (CPT Codes 78264, 78265, and 78266)

In establishing CY 2016 interim final values, we accepted the RUC-recommended work RVUs for CPT codes 78265 and 78266. We believed that the RUC-recommended RVU of 0.80 overestimated the work involved in furnishing CPT code 78264 and as a result, we established an interim final work RVU of 0.74 based on a crosswalk to CPT code 78226 (hepatobiliary system imaging, including gallbladder when present), due to similar intraservice times and intensities.

Comment: Commenters did not support our interim final work RVU for CPT code 78264. Commenters disagreed with our assessment of CPT code 78264 as having a higher work RVU and shorter intraservice time relative to the other codes in the family. One commenter stated that a difference of two minutes in intraservice time was insignificant and should not be used as a rationale for revaluing. Another commenter stated that we should have maintained the RUC-recommended crosswalk of CPT code 78264 to CPT code 78227 (Hepatobiliary system imaging, including gallbladder when present; with pharmacologic intervention, including quantitative measurement(s) when performed) due to similarities in service, work and intensity. Based on these concerns, commenters requested that CPT code 78264 be referred to the refinement panel.

Response: CPT code 78264 was referred to the CY 2016 multi-specialty refinement panel for further review. We calculate the refinement panel results as the median of each vote. That result for CPT code 78264 was 0.79 RVUs. After consideration of the comments and the refinement panel results, we agree that 0.79 accurately captures the overall work involved in furnishing this service and are proposing a value of 0.79 for CPT code 78264.

(18) Cytopathology Fluids, Washings or Brushings and Cytopathology Smears, Screening, and Interpretation (CPT Codes 88104, 88106, 88108, 88112, 88160, 88161, and 88162)

In the CY 2016 PFS final rule with comment period, we made a series of refinements to the recommended direct PE inputs for this family of codes. We removed the equipment time for the solvent recycling system (EP038) and the associated clinical labor described by the tasks "Recycle xylene from stainer" and "Order, restock, and distribute specimen containers and or slides with requisition forms" due to our belief that these were forms of indirect PE. This refinement applied to all seven codes in the family. We also noticed what appeared to be an error in the quantity of non-sterile gloves (SB022), impermeable staff gowns (SB027), and eye shields (SM016) assigned to CPT codes 88108 and 88112. The recommended value of these supplies was a quantity of 0.2, which we believed was intended to be a quantity of 2. We therefore refined the value of these supplies to 2 for CPT codes 88108 and 88112.

Comment: Several commenters disagreed with our characterization of the solvent recycling system and its associated clinical labor tasks as indirect PE. Commenters stated that the solvent recycling system costs are direct expenses since they are based on the amount of recycled solvent allocated to each specimen, with solvents allocated to specific specimens based on batch size. They indicated that the related clinical labor tasks are also forms of direct PE as they are also based on the amount of recycled solvent allocated to each specimen. The time for these tasks varies based on the batch size, which varies by procedure.

Response: We maintain our previously stated belief that these are forms of indirect PE, as they are not allocated to any individual service. We have defined direct PE inputs as clinical labor, medical supplies, or medical equipment that are individually allocable to a particular patient for a particular service. We continue to believe that a solvent recycling system would be in general use for a lab practice, and that the associated clinical labor tasks for ordering and restocking specimen containers can be more accurately described as administrative activities. We are proposing to maintain these refinements from the previous rulemaking cycle for CPT codes 88104–88162.

Comment: A commenter indicated that we did not account for the batch size when considering the supply quantities for CPT codes 88108 and 88112. The commenter indicated that the practice expense inputs should be assumed to have a batch size of five for these two codes, and therefore, no edits should be made. The commenter requested that we restore the quantity of 0.2 for the gloves, gowns, and eye shields associated with these procedures. This did not apply to the other codes on the submitted spreadsheet, which had a batch size of one.

Response: We appreciate the assistance of the commenter in clarifying the batch size for these procedures. As a result, we are proposing to refine the supply quantity of the non-sterile gloves (SB022), impermeable staff gowns (SB027), and eye shields (SM016) back to the RUC-recommended value of 0.2 for CPT codes 88108 and 88112.

(19) Immunohistochemistry (CPT Codes 88341, 88342, 88344, and 88350)

In the CY 2014 PFS final rule with comment period (78 FR 74341), we assigned a status indicator of I (Not valid for Medicare purposes) to CPT codes 88342 and 88343 and instead created two G-codes, G0461 and G0462, to report immunohistochemistry services. We did this in part to avoid creating incentives for overutilization. For CY 2015, the CPT coding was revised with the creation of two new CPT codes, 88341 and 88344, the revision of CPT code 88342 and the deletion of CPT code 88343. In the past for similar procedures in this family, the RUC recommended a work RVU for the add-on code (CPT code 88364) that was 60 percent of the base code (CPT code 88365). In the CY 2015 PFS final rule with comment period, we stated that the relative resources involved in furnishing an add-on service in this family would be reflected appropriately using the same 60 percent metric and subsequently established an interim final work RVU of 0.42 for CPT code 88341, which was 60 percent of the work RVU of the base CPT code 88342 (0.70). In the CY 2016 PFS proposed rule, we revised the add-on codes from 60 percent to 76 percent of the base code and subsequently revalued CPT code 88341 at 0.53 work RVUs. However, we inadvertently published work RVUs for CPT code 88341 in Addendum B without explicitly discussing it in the preamble text. In the CY 2016 PFS final rule with comment period, we maintained CPT code 88341's CY 2015 work RVU of 0.53 as interim final for CY 2016 and requested public comment. Also, in the CY 2016 PFS final rule with comment period, we established an interim final value of 0.70 work RVUs for CPT codes 88342 and 88344.

Comment: Several commenters expressed their opposition to a standard discount for the physician work involved in pathology add-on services and urged us to accept the RUC-recommend value of 0.65 RVUs for CPT code 88341.

Response: We appreciate commenters' concerns regarding a standard discount; however, we believe that it is reasonable to estimate work RVUs for a base and an add-on code, and to recognize efficiencies between them, by looking at how similar efficiencies are reflected in work RVUs for other PFS services. Also we note that the intravascular codes for which we initially established our base/add-on code relationship for CPT codes 88346 and 88350 were deleted in CY 2016 and replaced with two new codes; CPT codes 37252 and 37253. The relationship between 37252 and 37253 represents a 20 percent discount for the add-on code as the base CPT code 37252 has a work RVU of 1.80 and 37523 and work RVU of 1.44. As CPT codes 37252 and 37253 replaced the codes on which our discounts for base and add-on codes were based (please see the CY 2016 PFS final rule with comment period (80 FR 70972) for a detailed discussion) we believed it would be appropriate to maintain the same 20 percent relationship for 88346 and 88350. Therefore, for CY 2017, we are proposing a work RVU of 0.56 for CPT code 88341, which represents 80 percent of 0.70, the work RVU of the base code.

For CY 2016, we finalized a work RVU of 0.56 for CPT code 88350 which represented 76 percent of 0.74, the RVU for the base code. To maintain consistency within this code family, we are proposing to revalue CPT code 88350 using the 20 percent discount discussed above. To value CPT code 88350, we multiplied the work RVU of CPT code 88346, 0.74, by 80 percent, and then subtracted the product from 0.74, resulting in a work RVU of 0.59 for CPT code 88350. Therefore, for CY 2017, we are proposing a work RVU of 0.59 for CPT code 88350.

A stakeholder has suggested to us that an error was made in the implementation of direct PE inputs for code 88341 and several other related codes. This stakeholder stated that when CMS reclassified equipment code EP112 (Benchmark ULTRA automated slide preparation system) and EP113 (E-Bar II Barcode Slide Label System) into a single equipment item, with a price of $150,000 using equipment code EP112, the equipment minutes assigned to the E-Bar II Barcode Slide Label System should have been added into the new EP112 equipment time. The stakeholder requested that these minutes should be added into the EP112 equipment time; for example, 1 additional minute should be added to CPT code 88341 for a total of 16 minutes.

We appreciate the additional information, and are soliciting additional information on this topic through public comment on this proposed rule to assess whether it would be appropriate to add the former EP113 minutes into EP112. We are specifically seeking comment from other stakeholders, including the RUC, since the assigned number of minutes was originally based on a RUC recommendation. This information would be potentially relevant for CPT codes 88341 (Immunohistochemistry or immunocytochemistry, per specimen; each additional single antibody stain procedure), 88342 (Immunohistochemistry or immunocytochemistry, per specimen; initial single antibody stain procedure), 88344 (Immunohistochemistry or immunocytochemistry, per specimen; each multiplex antibody stain procedure), 88360 (Morphometric analysis, tumor immunohistochemistry, quantitative or semiquantitative, per specimen, each single antibody stain procedure; manual), and 88361 (Morphometric analysis, tumor immunohistochemistry, quantitative or semiquantitative, per specimen, each single antibody stain procedure; using computer-assisted technology).

(20) Morphometric Analysis (CPT Codes 88364, 88365, 88367, 88368, 88369 and 88373)

For CY 2015, the CPT editorial panel revised the code descriptors for the in situ hybridization procedures, CPT codes 88365, 88367 and 88368, to specify "each separately identifiable probe per block." Additionally, three new add-on codes (CPT codes 88364, 88369, 88373,) were created to specify "each additional separately identifiable probe per slide." Some of the add-on codes in this family had RUC-recommended work RVUs that were 60 percent of the work RVU of the base procedure. We believed this accurately reflected the resources used in furnishing these add-on codes and subsequently established interim-final work RVUs of 0.53 for code 88364 (60 percent of the work RVU of CPT code 88365); 0.53 for CPT code 88369 (60 percent of the work RVU of CPT code 88368); and 0.43 for CPT code 88373 (60 percent of the work RVU of CPT code 88367).

For CY 2016, the RUC re-reviewed these services due to the specialty society's initially low survey response rate. In our review of these codes, we noticed that the latest RUC recommendation was identical to the RUC recommendation provided for CY 2015. Therefore, we proposed to retain the CY 2015 work RVUs and work time for CPT codes 88367 and 88368 for CY 2016. For CPT code 88365 we finalized a work RVU of 0.88.

For CPT codes 88364 and 88369, we increased the work RVUs of these add-on codes from 0.53 to 0.67, which reflected 76 percent of the work RVUs of the base procedures for these services. However, we inadvertently omitted the rationale for this revision to the work RVUs in the proposed rule. Consequently, we maintained the CY 2015 interim final values of the work RVU of 0.67 for CPT codes 88464 and 88369 and sought comment on these values for CY 2016. For CPT code 88373 we finalized a work RVU of 0.43.

Comment: A few commenters stated their objection to our use of a standard discount for pathology add-on services and for suggesting that each service is separate and unique. Commenters also stated there should be no comparison of intravascular ultrasound services to morphometric analysis, immunohistochemistry, immunofluorescence, or any pathology service.

Response: In reviewing the RUC-recommended base/add-on relationships between several pathology codes, we continue to believe the base/add-on code time relationships for pathology services are appropriate and have not been presented with any compelling evidence that conflicts with the RUC-recommended relationships. However, as we stated above, the intravascular codes we initially examined in revaluing CPT codes 88364 and 88369 were deleted in CY 2016 and replaced with CPT codes 37252 and 37253. For the reasons stated above we continue to believe this 20 percent discount relationship between the base and add-on code accurately reflects the work involved in furnishing these services.

Therefore, for CY 2017, we are proposing a work RVU of 0.70 for CPT codes 88364 and 88369 which represents a 20 percent discount from the base code. As the relationship between the base code and add-on code now represents a 20 percent difference we are proposing to revalue CPT code 88373 at 0.58 work RVUs. Therefore, for CY 2017 we are proposing a work RVU of 0.58 for CPT code 88373.

(21) Liver Elastography (CPT Code 91200)

For CY 2016, we received a RUC recommendation of 0.27 RVU for CPT code 91200. After careful review of the recommendation, we established the RUC-recommended work RVU and direct PE inputs as interim final for CY 2016.

Comment: A few commenters requested that we reconsider the level of payment assigned to this service when furnished in a non-facility setting, stating that the code met the definition for the potentially misvalued code list as there is a significant difference in payment between sites of service. The commenters also asked us to reconsider the assigned 50 percent utilization rate for the FibroScan equipment in this procedure as the current utilization rate would translate to over 50 procedures per week. Instead, the commenters suggested the typical number of procedures done per week ranges between 15 and 25 and requested we adopt a 25 percent utilization rate which corresponds to that number of procedures.

Response: We refer commenters to the CY 2016 final rule with comment period (80 FR 71057–71058) where we discussed and addressed the comparison of the PFS payment amount to the OPPS payment amount for CPT 91200. For the commenter's statement about the utilization rate, we have previously addressed the accuracy of these default assumptions as they apply to particular equipment resources and particular services. In the CY 2008 PFS proposed rule (72 FR 38132), we discussed the 50 percent utilization assumption and acknowledged that the default 50 percent usage assumption is unlikely to capture the actual usage rates for all equipment. However, we stated that we did not believe that we had strong empirical evidence to support any alternative approaches. We indicated that we would continue to monitor the appropriateness of the equipment utilization assumption, and evaluate whether changes should be proposed in light of the data available. The commenters did not provide any verifiable data suggesting a lower utilization rate. Therefore, for CY 2017 we are proposing a work RVU of 0.27 for CPT code 91200, consistent with the CY 2016 interim final value, and we continue to explore and seek comments regarding publicly available data sources to identify the most accurate equipment utilization rate assumptions possible. We also note that following the publication of the CY 2016 PFS final rule with comment period (80 FR 70886) there was an inconsistency in the Work Time file published on the CMS Web site. For CPT code 91200 the RUC recommended 16 minutes total service time whereas our file reflected 18 minutes total time for the service. For CY 2017, we are proposing to update the Work Time file to reflect the RUC's recommendation, which is 16 minutes for CPT code 91200.

b. CY 2017 Proposed Codes

(1) Anesthesia Services Furnished in Conjunction with Lower Gastrointestinal (GI) Procedures (CPT Codes 00740 and 00810)

The anesthesia procedure CPT codes 00740 and 00810 are used for anesthesia furnished in conjunction with lower gastrointestinal (GI) procedures. In the CY 2016 PFS proposed rule (80 FR 41686), we discussed that in reviewing Medicare claims data, a separate anesthesia service is now reported more than 50 percent of the time that several types of colonoscopy procedures are reported. We discussed that given the significant change in the relative frequency with which anesthesia codes are reported with colonoscopy services, we believe the relative values of the anesthesia services should be reexamined. We proposed to identify CPT codes 00740 and 00810 as potentially misvalued and sought public comment regarding valuation for these services.

The RUC recommended maintaining the base unit value of 5 as an interim base value for both CPT code 00740 and 00810 on an interim basis, due to their concerns about the specialty society surveys. The RUC suggested that the typical patient vignettes used in the surveys for both CPT codes 00740 and 00810 were not representative of current typical practice and recommended that the codes be resurveyed with updated vignettes. We agree that it is premature to propose any changes to the valuation of CPT codes 00740 and 00810, but continue to believe that these services are potentially misvalued and look forward to receiving input from interested parties and specialty societies for consideration during future notice and comment rulemaking.

(2) Removal of Nail Plate (CPT Code 11730)

We identified CPT code 11730 (Avulsion of nail plate, partial or complete, simple; single) through a screen of high expenditures by specialty. The HCPAC recommended a work RVU of 1.10. We believe the recommendation for this service overestimates the work involved in performing this procedure, specifically given the decrease in physician intraservice and total time concurrently recommended by the HCPAC. We believe that a work RVU of 1.05, which corresponds to the 25th percentile of the survey results, more accurately represents the time and intensity of furnishing the service. To further support the validity of the use of the 25th percentile of the survey, a work RVU of 1.05, we identified two crosswalk CPT codes, 20606 (Arthrocentesis, aspiration and/or injection, intermediate joint or bursa), with a work RVU of 1.00, and 50389 (Removal of nephrostomy tube, requiring fluoroscopic guidance) with a work RVU of 1.10, both of which have identical intraservice times, similar total times and similar intensity. We note that our proposed work RVU of 1.05 for CPT code 11730 falls halfway between the work RVUs for these two crosswalk-codes. CPT Code 11730 may be reported with add-on CPT code 11732 to report performance of the same procedure for each additional nail plate procedure.

Since CPT code 11732 was not reviewed by the HCPAC for CY 2017, we are proposing a new work value to maintain the consistency of this add-on code with the base code, CPT code 11730. We are proposing to remove 2 minutes from the physician intraservice time to maintain consistency with the HCPAC-recommended reduction of 2 minutes from the physician intraservice time period for the base code. We are using a crosswalk from the value for CPT code 77001 (Fluoroscopic guidance for central venous access device placement, replacement (catheter only or complete), or removal (includes fluoroscopic guidance for vascular access and catheter manipulation, any necessary contrast injections through access site or catheter with related venography radiologic supervision and interpretation, and radiographic documentation of final catheter position) (List separately in addition to code for primary procedure)), which has similar physician intraservice and total time values; therefore, we are proposing a work RVU of 0.38 for CPT code 11732. As further support for this proposal, we note that this proposed RVU reduction is similar to the value obtained by subtracting the incremental difference in the current and recommended work RVUs for the base code from the current value of CPT code 11732.

We are proposing to use the HCPAC-recommended direct PE inputs for CPT code 11730. We are proposing to apply some of HCPAC-recommended refinements for CPT code 11730 to11732, including the removal of the penrose drain (0.25in x 4in), lidocaine 1%–2% inj (Xylocaine), applicator (cotton-tipped, sterile) and silver sulfadiazene cream (Silvadene), as well as the reduction of the swab-pad, alcohol from 2 to 1. In addition, we are proposing not to include the recommended the supply items "needle, 30g, and syringe, 10–12ml" since other similar items are present, and we think inclusion of these additional supply items would be duplicative. For clinical labor, we are proposing to assign 8 minutes to "Assist physician in performing procedure" for to maintain a reduction that is proportionate to that recommended for 11730. For the supply item "ethyl chloride spray," we believe that the listed input price of $4.40 per ounce overestimates the cost of this supply item, and we are seeking comment on the accuracy of this supply item price. Finally, we are adding two equipment items as was done in the base code, basic instrument pack and mayo stand, and are proposing to adjust the times for all pieces of equipment to 8 minutes to reflect the clinical service period time.

(3) Bone Biopsy Excisional (CPT Code 20245)

In CY 2014, CPT code 20245 was identified by the RUC's 10-Day Global Post-Operative Visits Screen.

For CY 2017, the RUC recommended a value of 6.50 work RVUs for CPT code 20245, including a change in global period from 10- to 0- days. We disagree with this value given the significant reductions in the intraservice time, total time, and the change in the office visits assuming the change in global period. The intraservice and total times were decreased by approximately 33 and 53 percent respectively; while the elimination of three post-operative visits (one CPT code 99214 and two CPT code 99213 visits) alone would reduce the overall work RVU by at least 38 percent under the reverse building block methodology. We also note that the RUC-recommended work RVU of 6.50 only represents a 27 percent reduction relative to the previous work RVU of 8.95. To develop a work RVU for this service, we used a crosswalk from CPT code 19298 (Placement of radiotherapy after loading brachytherapy catheters (multiple tube and button type) into the breast for interstitial radioelement application following (at the time of or subsequent to) partial mastectomy, includes imaging guidance), since we believe the codes share similar intensity and total time and the same intraservice time of 60 minutes. Therefore, for CY

2017, we are proposing a work RVU of 6.00 for CPT code 20245.

(4) Insertion of Spinal Stability Distractive Device (CPT Codes 228X1, 228X2, 228X4, and 228X5)

For CY 2016, the CPT Editorial Panel converted two Category III codes to Category I codes describing the insertion of an interlaminar/interspinous process stability device (CPT codes 228X1 and 228X4) and developed two corresponding add-on codes (CPT codes 228X2 and 228X5). The RUC recommended a work RVU of 15.00 for CPT code 228X1, 4.00 for CPT code 228X2, 7.39 for CPT code 228X4, and 2.34 for CPT code 228X5.

We believe that the RUC recommendations for CPT codes 228X1 and 228X4 overestimate the work involved in furnishing these services. We believe that a crosswalk to CPT code 36832 (Revision, open, arteriovenous fistula; without thrombectomy, autogenous or nonautogenous dialysis graft (separate procedure)) which has a work RVU of 13.50 is an accurate comparison. CPT code 36832 is similar in total time, work intensity, and number of visits to 228X1. This is supported by the ratio between total time and work in the key reference service, CPT code 63047 (Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [e.g., spinal or lateral recess stenosis]), single vertebral segment; lumbar). Therefore, we are proposing a work RVU of 13.50 for CPT code 228X1. For CPT code 228X4, we believe that CPT code 29881 (Arthroscopy, knee, surgical; with meniscectomy (medial OR lateral, including any meniscal shaving) including debridement/shaving of articular cartilage (chondroplasty), same or separate compartment(s), when performed) is an appropriate crosswalk based on clinical similarity as well as intensity and total time. CPT code 29881 has an RVU of 7.03; therefore, we are proposing a work RVU of 7.03 for CPT code 228X4. We are proposing to accept the RUC-recommended work RVU for CPT codes 228X2 and 228X5 without refinement.

(5) Biomechanical Device Insertion (CPT Codes 22X81, 22X82, and 22X83)

For CY 2016, the CPT Editorial Panel established three new category I add-on codes and deleted one code to provide a more detailed description of the placement and attachment of biomechanical spinal devices. For CPT code 22X81, the RUC recommended a work RVU of 4.88. For CPT code 22X82, and CPT code 22X83, the recommended work RVUs are 5.50 and 6.00, respectively.

In reviewing the code descriptors, descriptions of work and vignettes associated with CPT codes 22X82 and 22X83, we determined that the two procedures, in addition to having identical work time, contain many clinical similarities and do not have quantifiable differences in overall intensity. Therefore, we are proposing the RUC-recommended work RVU of 5.50 for both CPT code 22X82 and CPT code 228X3. We believe that the RUC-recommended work RVU for CPT code 22X81 overestimates the work in the procedure relative to the other codes in the family. We are proposing a work RVU of 4.25 for CPT code 228X1 based a crosswalk from CPT code 37237 (Transcatheter placement of an intravascular stent(s) (except lower extremity artery(s) for occlusive disease, cervical carotid, extracranial vertebral or intrathoracic carotid, intracranial, or coronary), open or percutaneous, including radiological supervision and interpretation and including all angioplasty within the same vessel, when performed; each additional artery (List separately in addition to code for primary procedure)), which is similar in time and intensity to the work described by CPT code 22X81.

(6) Closed Treatment of Pelvic Ring Fracture (CPT Codes 271X1 and 271X2)

For CY 2017, the CPT Editorial Panel deleted CPT codes 27193 and 27194 and replaced them with two new codes, 271X1 and 271X2, and the RUC recommended a work RVU of 5.50 for CPT code 27193, and a work RVU of 9.00 for CPT code 271X2 to describe closed treatment of pelvic ring fracture. We are proposing to change the global period for these services from 90 days to 0 days because these codes typically represent emergent procedures with which injuries beyond pelvic ring fractures are likely to occur; we believe it is typical that multiple practitioners would be involved in providing post-operative care and it is likely that a practitioner furnishing a different procedure is more likely to be providing the primary post-operative care. If other practitioners are typically furnishing care in the post-surgery period, we believe that the six postservice visits included in CPT code 271X1, and the seven included in 271X2, would likely not occur. This is similar to our CY 2016 review and valuation of CPT codes 21811 (Open treatment of rib fracture(s) with internal fixation, includes thoracoscopic visualization when performed, unilateral; 1–3 ribs), 21812 (Open treatment of rib fracture(s) with internal fixation, includes thoracoscopic visualization when performed, unilateral; 4–6 ribs), and 21813 (Open treatment of rib fracture(s) with internal fixation, includes thoracoscopic visualization when performed, unilateral; 7 or more ribs). In our valuation of those codes, we determined that a 0-day, rather than a 90-day global period was preferable, in part because those codes describe rib fractures that would typically occur along with other injuries, and the patient would likely already be receiving post-operative care because of the other injuries. We believe that the same rationale applies here. To establish a work RVU for 271X1, we are crosswalking this code to CPT code 65800 (Paracentesis of anterior chamber of eye (separate procedure); with removal of aqueous), due to its identical intraservice time and similar total time, after removing the work associated with postoperative visits, and its similar level of intensity. Therefore, we are proposing a work RVU of 1.53 for CPT code 271X1. For 271X2, we are crosswalking to CPT code 93452 (Left heart catheterization including intraprocedural injection(s) for left ventriculography, imaging supervision and interpretation, when performed) which has an identical intraservice time and similar total time after removing the work associated with postoperative visits from 271X2. We are proposing a work RVU of 4.75 for code 271X2.

(7) Bunionectomy (CPT Codes 28289, 282X1, 28292, 28296, 282X2, 28297, 28298, and 28299)

The RUC identified CPT Code 28293 as a 90-day global service with more than 6 office visits and CPT codes 28290–28299 as part of the family of services. In October 2015, the CPT Editorial Panel created two new CPT codes (282X1, 282X2), deleted CPT codes 28290, 28293, 28294 and revised CPT codes 28289, 28292, 28296, 28297, 28298 and 28299 based on the rationale that more accurate descriptions of the services needed to be developed.

For CPT codes 28289, 28292, 28296, 28297, 28298, and 28299 the RUC recommended and we are proposing work RVUs of 6.90, 7.44, 8.25, 9.29, 7.75, and 9.29 respectively. For CPT code 282X1, the RUC recommended a work RVU of 8.01 based on the 25th percentile of the survey. We believe the recommendation for this service overestimates the overall work involved in performing this procedure given the decrease in intraservice time, total time, and post-operative visits when compared to deleted predecessor CPT code 28293. Due to similarity in intraservice and total times, we believe a direct crosswalk of the work RVUs for CPT code 65780 (Ocular surface reconstruction; amniotic membrane transplantation, multiple layers), to CPT code 282X1 more accurately reflects the time and intensity of furnishing the service. Therefore, for CY 2017, we are proposing a work RVU of 7.81 for CPT code 282X1.

For CPT code 282X2, the RUC recommended a work RVU of 8.57 based on the 25th percentile of the survey. We believe the recommendation for this service overestimates the work involved in performing this procedure given the similarity in the intensity of the services and identical intraservice and total times as CPT code 28296. Therefore, we propose a direct RVU crosswalk from CPT code 28296 to CPT code 282X2. For CY 2017, we are proposing a work RVU of 8.25 for CPT code 282X2.

(8) Endotracheal Intubation (CPT Code 31500)

In the CY 2016 PFS final rule with comment period (80 FR 70914), we identified CPT code 31500 as potentially misvalued. The specialty societies surveyed this code, and after reviewing the survey responses, including increases in time, the RUC recommended an increase in work RVUs to 3.00 for CPT code 31500. After reviewing the RUC's recommendation, we are proposing a work RVU of 2.66, based on a direct crosswalk to CPT code 65855, which has similar intensity and service times as reflected in the survey data reported by the specialty groups.

(9) Closure of Left Atrial Appendage With Endocardial Implant (CPT Code 333X3)

The CPT Editorial Panel deleted category III code 0281T (Percutaneous transcatheter closure of the left atrial appendage with implant, including fluoroscopy, transseptal puncture, catheter placement(s), left atrial angiography, left atrial appendage angiography, radiological supervision and interpretation) and created new CPT code 333X3 to describe percutaneous transcatheter closure of the left atrial appendage with implant. The RUC recommended a work RVU of 14.00, which is the 25th percentile survey result. After reviewing that recommendation, we are proposing a work RVU of 13.00 for CPT code 333X3, which is the minimum survey result. Based on our clinical judgment and that the key reference codes discussed in the RUC recommendations have higher intraservice and total service times than the median survey results for CPT code 333X3, we believe a work RVU of 13.00 more accurately represents the work value for this service.

(10) Valvuloplasty (CPT Codes 334X1 and 334X2)

The CPT Editorial Committee created new codes to describe valvuloplasty procedures and deleted existing CPT code 33400 (Valvuloplasty, aortic valve; open, with cardiopulmonary bypass). New CPT code 334X1 represents a simple valvuloplasty procedure and new CPT code 334X2 describes a more complex valvuloplasty procedure. We are proposing to use the RUC-recommended values for CPT code 334X1. For CPT code 334X2, the RUC recommended a work RVU of 44.00, the 25th percentile survey result. The RUC estimated that approximately 70 percent of the services previously reported using CPT code 33400 would have been reported using CPT code 334X2 with 30 percent reported using new CPT code 334X1. Therefore, the typical service previously reported with 33400 ought to now be reported with 334X2. Compared to deleted CPT code 33400, the survey results for CPT 334X2 showed the median intraservice time to be similar but total service time to be decreased. Therefore, we do not believe the increase recommended by the RUC is warranted, and we are proposing a work RVU of 41.50 for CPT code 334X2. This is the current value of CPT code 33400, and given that the typical service should remain consistent between the two codes, we believe the work RVU should remain consistent as well.

(11) Dialysis Circuit (CPT Codes 369X1, 369X2, 369X3, 369X4, 369X5, 369X6, 369X7, 369X8, 369X9)

In January 2015, a CPT/RUC workgroup identified the following CPT codes as being frequently reported together in various combinations: 35475 (Transluminal balloon angioplasty, percutaneous; brachiocephalic trunk or branches, each vessel), 35476 (Transluminal balloon angioplasty, percutaneous; venous), 36147 (Introduction of needle and/or catheter, arteriovenous shunt created for dialysis (graft/fistula); initial access with complete radiological evaluation of dialysis access, including fluoroscopy, image documentation and report), 36148 (Introduction of needle and/or catheter, arteriovenous shunt created for dialysis (graft/fistula); additional access for therapeutic intervention), 37236 (Transcatheter placement of an intravascular stent(s) (except lower extremity artery(s) for occlusive disease, cervical carotid, extracranial vertebral or intrathoracic carotid, intracranial, or coronary), open or percutaneous, including radiological supervision and interpretation and including all angioplasty within the same vessel, when performed; initial artery), 37238 (Transcatheter placement of an intravascular stent(s), open or percutaneous, including radiological supervision and interpretation and including angioplasty within the same vessel, when performed; initial vein), 75791 (Angiography, arteriovenous shunt (*e.g.*, dialysis patient fistula/graft), complete evaluation of dialysis access, including fluoroscopy, image documentation and report (includes injections of contrast and all necessary imaging from the arterial anastomosis and adjacent artery through entire venous outflow including the inferior or superior vena cava), radiological supervision and interpretation), 75962 (Transluminal balloon angioplasty, peripheral artery other than renal, or other visceral artery, iliac or lower extremity, radiological supervision and interpretation), and 75968 (Transluminal balloon angioplasty, each additional visceral artery, radiological supervision and interpretation). These codes are frequently reported together for both dialysis circuit services and transluminal angioplasty services. At the October 2015 CPT Editorial Panel meeting, the panel approved the creation of nine new codes and deletion of four existing codes used to describe bundled dialysis circuit intervention services, and the creation of four new codes and deletion of 13 existing codes used to describe bundled percutaneous transluminal angioplasty services (see discussion of the latter code family in the next section). The Dialysis Circuit family of codes overlaps with the Open and Percutaneous Transluminal Angioplasty family of codes (CPT codes 372X1–372X4), as they are both being constructed from the same set of frequently reported together codes. We reviewed these two families of codes concurrently to maintain relativity between these clinically similar procedures based upon the same collection of deleted codes.

For CPT code 369X1, we are proposing a work RVU of 2.82 instead of the RUC-recommended work RVU of 3.36. When we compared CPT code 369X1 against other codes in the RUC database, we found that the RUC-recommended work RVU of 3.36 would be the highest value in the database among the 32 0-day global codes with 25 minutes of intraservice time. Generally speaking, we are particularly skeptical of RUC-recommended values for newly "bundled" codes that appear not to recognize the full resource overlap between predecessor codes. Since the recommended values would establish a new highest value when compared to other services with similar time, we believe it likely that the recommended value for the new code does not reflect the efficiencies in time. Of course, were the compelling evidence for this valuation accompanying the recommendation, we would consider such information. We also note that the reference code selected by the survey participants, CPT code 36200 (Introduction of catheter, aorta), has a higher intraservice time and total time, but a lower work RVU of 3.02. We believe that there are more accurate CPT codes that can serve as a reference for CPT code 369X1. As a result, we are proposing to crosswalk CPT code 369X1 to CPT code 44388 (Colonoscopy through stoma; diagnostic). CPT code 44388 has a work RVU of 2.82, and we believe it is a more accurate crosswalk for valuation due to its similar overall intensity and shared intraservice time of 25 minutes with 369X1 and similar total time of 65 minutes.

We are proposing a work RVU of 4.24 for CPT code 369X2 instead of the RUC-recommended work RVU of 4.83. The RUC-recommended work RVU is based upon a direct crosswalk to CPT code 43253 (Esophagogastroduodenoscopy, flexible, transoral) which shares the same 40 minutes of intraservice time with CPT code 369X2. However, CPT code 43253 has significantly longer total time than CPT code 369X2, 104 minutes against 86 minutes, which we believe reduces its utility for comparison. We are instead proposing to crosswalk the work RVU for CPT code 369X2 from CPT code 44408 (Colonoscopy through stoma), which has a work RVU of 4.24. In addition to our assessment that the two codes share similar intensities, CPT code 44408 also shares 40 minutes of intraservice time with CPT code 369X2 but has only 95 minutes of total time and matches the duration of the procedure under review more closely than the RUC-recommended crosswalk to CPT code 43253. We also note that the RUC-recommended work increment between CPT codes 369X1 and 369X2 was 1.47, and by proposing a work RVU of 4.24 for CPT code 369X2, we maintain a very similar increment of 1.42. As a result, we are proposing a work RVU of 4.24 for CPT code 369X2, based on this direct crosswalk to CPT code 44408.

For CPT code 369X3, we are proposing a work RVU of 5.85 instead of the RUC-recommended work RVU of 6.39. The RUC-recommended value is based on a direct crosswalk to CPT code 52282 (Cystourethroscopy, with insertion of permanent urethral stent). Like the previous pair of RUC-recommended crosswalk codes, CPT code 52282 shares the same intraservice time of 50 minutes with CPT code 369X3, but has substantially longer total time (120 minutes against 96 minutes) which we believe limits its utility as a crosswalk. We are proposing a work RVU of 5.85 based on maintaining the RUC-recommended work RVU increment of 3.03 as compared to CPT code 369X1 (proposed at a work RVU of 2.82), the base code for this family of related procedures. We also point to CPT code 44403 (Colonoscopy through stoma; with endoscopic mucosal resection) as a reference point for this value. CPT code 44403 has a work RVU of 5.60, but also lower intraservice time (45 minutes as compared to 50 minutes) and total time (92 minutes as compared to 96 minutes) in relation to CPT code 369X3, suggesting that a work RVU a bit higher than 5.60 would be an accurate valuation. Therefore, we are proposing a work RVU of 5.85 for CPT code 369X3, based on an increment of 3.03 from the work RVU of CPT code 369X1.

We are proposing a work RVU of 6.73 instead of the RUC-recommended work RVU of 7.50 for CPT code 369X4. Our proposed value comes from a direct crosswalk from CPT code 43264 (Endoscopic retrograde cholangiopancreatography), which shares the same intraservice time of 60 minutes with CPT code 369X4 and has a higher total time. We also looked to the intraservice time ratio between CPT codes 369X1 and 369X4; this works out to 60 minutes divided by 25 minutes, for a ratio of 2.4, and a suggested work RVU of 6.77 (derived from 2.4 times CPT code 369X1's work RVU of 2.82). This indicates that our proposed work RVU of 6.73 maintains relativity within the Dialysis Circuit family. As a result, we are proposing a work RVU of 6.73 for CPT code 369X4, based on a direct crosswalk to CPT code 43264.

We are proposing a work RVU of 8.46 instead of the RUC-recommended work RVU of 9.00 for CPT code 369X5. We looked at the intraservice time ratio between CPT codes 369X1 and 369X5 as one potential method for valuation, which is a 1:3 ratio (25 minutes against 75 minutes) for this case. This means that one potential value for CPT code 369X5 would be triple the work RVU of CPT code 369X1, or 2.82 times 3, which results in a work RVU of 8.46. We also investigated preserving the RUC-recommended work RVU increment between CPT code 369X1 and 369X5, which was an increase of 5.64. When this increment is added to the work RVU of 2.82 for CPT code 369X1, it also resulted in a work RVU of 8.46 for CPT code 369X5. Therefore, we are proposing a work RVU of 8.46 for CPT code 369X5, based on both the intraservice time ratio with CPT code 369X1 and the RUC-recommended work increment with the same code.

For CPT code 369X6, we are proposing a work RVU of 9.88 instead of the RUC-recommended work RVU of 10.42. We based the proposed value upon the RUC-recommended work RVU increment between CPT codes 369X1 and 369X6, which is 7.06. When added to the work RVU of 2.82 for CPT code 369X1, the work RVU for CPT code 369X6 would be 9.88. We are supporting this value through the use of two crosswalks that both share the same 90 minutes of intraservice time with 369X6. These are CPT code 31546 (Laryngoscopy, direct, with submucosal removal of non-neoplastic lesion(s) of vocal cord) at a work RVU of 9.73 and CPT code 61623 (Endovascular temporary balloon arterial occlusion, head or neck) at a work RVU of 9.95.

The final three codes in the Dialysis Circuit family are all add-on codes, which make comparisons difficult to the global 0-day codes that make up the rest of the family. We are proposing a work RVU of 2.48 instead of the RUC-recommended work RVU of 3.00 for CPT code 369X7. Due to the difficulty of comparing CPT code 369X7 with the non-add-on codes in the rest of the Dialysis Circuit family, we looked instead to compare the value to the add-on codes in the Open and Percutaneous Transluminal Angioplasty family of codes (CPT codes 372X1–372X4). As we stated previously, both of these groups of new codes are being constructed from the same set of frequently reported together codes. We reviewed these two families of codes together to maintain relativity across the two families, and so that we could compare codes that shared the same global period.

We are proposing the RUC-recommended work RVUs for all four codes in the Open and Percutaneous Transluminal Angioplasty family of codes. As a result, we compared CPT code 369X7 with the RUC-recommended work RVU of 2.97 for CPT code 372X4, which is also an add-on code. These procedures should be clinically very similar, since both of them are performing percutaneous transluminal angioplasty on a central vein, and both of them are add-on procedures. We looked at the intraservice time ratio between these two codes, which was a comparison between 25 minutes for CPT code 369X7 against 30 minutes for CPT code 372X4.

This produces a ratio of 0.83, and a proposed work RVU of 2.48 for CPT code 369X7 when multiplied with the RUC-recommended work RVU of 2.97 for CPT code 372X4. We note as well that the intensity was markedly higher for CPT code 369X7 as compared to CPT code 372X4 when using the RUC-recommended work values, which did not make sense since CPT code 369X7 would typically be a clinically less intense procedure. Using the intraservice time ratio results in the two codes having exactly the same intensity. As a result, we are therefore proposing a work RVU of 2.48 for CPT code 369X7, based on this intraservice time ratio with the RUC-recommended work RVU of CPT code 372X4.

For CPT code 369X8, we disagree with the RUC-recommended work RVU of 4.25, and we are instead proposing a work RVU of 3.73. We do not consider the RUC work value of 4.25 to be accurate for CPT code 369X8, as this was higher than our proposed work value for CPT code 369X2 (4.24), and we do not believe that an add-on code should typically have a higher work value than a similar non-add-on code with the same intraservice time. We identified two appropriate crosswalks for valuing CPT code 369X8: CPT code 93462 (Left heart catheterization by transseptal puncture through intact septum or by transapical puncture) and CPT code 37222 (Revascularization, endovascular, open or percutaneous, iliac artery). Both of these codes share the same intraservice time as CPT code 369X8, and both of them also have the same work RVU of 3.73, which results in these codes also sharing the same intensity since they are all add-on codes. We are therefore proposing a work value of 3.73 for CPT code 369X8, based on a direct crosswalk to CPT codes 93462 and 37222.

Finally, we are proposing a work RVU of 3.48 for CPT code 369X9 instead of the RUC-recommended work RVU of 4.12. The RUC recommended value comes from a direct crosswalk from CPT code 38746 (Thoracic lymphadenectomy by thoracotomy). We compared the RUC-recommended work RVU for this procedure to other add-on codes with 30 minutes of intraservice time and found that the recommended work RVU of 4.12 would overestimate the overall intensity of this service relative to those with similar times. In reviewing the range of these codes, we believe that a more appropriate crosswalk is to CPT code 61797 (Stereotactic radiosurgery (particle beam, gamma ray, or linear accelerator)) at a work RVU of 3.48. We believe that this value is more accurate when compared to other add-on procedures with 30 minutes of intraservice time across the PFS. As a result, we are proposing a work RVU of 3.48 for CPT code 369X9 based on a direct crosswalk from CPT code 61797.

We are proposing to use the RUC-recommended direct PE inputs for these nine codes with several refinements. We are not proposing to include the recommended additional preservice clinical labor for CPT codes 369X4, 369X5, and 369X6. The preservice work description is identical for all six of the global 0-day codes in this family; there is no justification given in the RUC recommendations as to why the second three codes need additional clinical labor time beyond the minimal preservice clinical labor assigned to the first three codes. We do not believe that the additional staff time would be typical. Patient care already would have been coordinated ahead of time in the typical case, and the need for unscheduled dialysis or other unusual circumstances would be discussed prior to the day of the procedure. We are therefore proposing to refine the preservice clinical labor for CPT codes 369X4, 369X5, and 369X6 to match the preservice clinical labor of CPT codes 369X1, 369X2, and 369X3.

We are proposing to refine the L037D clinical labor for "Prepare and position patient/monitor patient/set up IV" from 5 minutes to 3 minutes for CPT codes 369X1–369X6. The RUC recommendation included a written justification for additional clinical labor time beyond the standard 2 minutes for this activity, stating that the extra time is needed to prepare the patient's arm for the procedure. We agree that extra time may be needed for this activity as compared to the default standard of 2 minutes; however, we are assigning 1 extra minute for preparing the patient's arm, resulting in a total of 3 minutes for this task. We do not believe that 3 extra minutes would be typically needed for arm positioning.

We are proposing to remove the "kit, for percutaneous thrombolytic device (Trerotola)" supply (SA015) from CPT codes 369X4, 369X5, and 369X6. We believe that this thrombolytic device kit and the "catheter, thrombectomy-Fogarty" (SD032) provide essentially the same supply, and the use of only one of them would be typical in these procedures. We believe that each of these supplies can be used individually for thrombectomy procedures. We are proposing to remove the SA015 supply and retain the SD032 supply, and we seek additional comment and information regarding the use of these two supplies.

We are also proposing to remove the recommended supply item "covered stent (VIABAHN, Gore)" (SD254) and replace it with the "stent, vascular, deployment system, Cordis SMART" (SA103) for CPT codes 369X3 and 369X6. The Cordis SMART vascular stent was previously used in the past for CPT code 37238, which is the deleted code for transcatheter placement of an intravascular stent that CPT codes 369X3 and 369X6 are replacing. We do not have a stated rationale as to the need for this supply substitution, and therefore, we do not believe it would be appropriate to replace the current items with a significantly higher-priced item without additional information.

We are also proposing to refine the quantity of the "Hemostatic patch" (SG095) from 2 to 1 for CPT codes 369X4, 369X5, and 369X6. This supply was not included in any of the deleted base codes out of which the new codes are being constructed, and while we agree that the use of a single hemostatic patch has become common clinical practice, we do not agree that CPT codes 369X4–369X6 would typically require a second patch. As a result, we are proposing to refine the SG095 supply quantity from 2 to 1 for CPT codes 369X4–369X6, which also matches the supply quantity for CPT codes 369X1–369X3.

Included in the RUC recommendation for the Dialysis Circuit family of codes were a series of invoices for a "ChloraPrep applicator (26 ml)" supply. We are soliciting comments regarding whether the Betadine solution has been replaced by a Chloraprep solution in the typical case for these procedures. We are also soliciting comments regarding whether the "ChloraPrep applicator (26 ml)" detailed on the submitted invoices is the same supply as the SH098 "chlorhexidine 4.0% (Hibiclens)" applicator currently in the direct PE database.

Finally, we are also interested in soliciting comments about the use of guidewires for these procedures. We are requesting feedback about which guidewires would be typically used for these procedures, and which guidewires are no longer clinically necessary.

(12) Open and Percutaneous Transluminal Angioplasty (CPT Codes 372X1, 372X2, 372X3, and 372X4)

In January 2015, a CPT/RUC workgroup identified the following CPT codes as being frequently reported together in various combinations: 35475 (Transluminal balloon angioplasty, percutaneous; brachiocephalic trunk or branches, each vessel), 35476 (Transluminal balloon angioplasty, percutaneous; venous), 36147 (Introduction of needle and/or catheter, arteriovenous shunt created for dialysis (graft/fistula); initial access with complete radiological evaluation of dialysis access, including fluoroscopy, image documentation and report), 36148 (Introduction of needle and/or catheter, arteriovenous shunt created for dialysis (graft/fistula); additional access for therapeutic intervention), 37236 (Transcatheter placement of an intravascular stent(s) (except lower extremity artery(s) for occlusive disease, cervical carotid, extracranial vertebral or intrathoracic carotid, intracranial, or coronary), open or percutaneous, including radiological supervision and interpretation and including all angioplasty within the same vessel, when performed; initial artery), 37238 (Transcatheter placement of an intravascular stent(s), open or percutaneous, including radiological supervision and interpretation and including angioplasty within the same vessel, when performed; initial vein), 75791 (Angiography, arteriovenous shunt (*e.g.*, dialysis patient fistula/graft), complete evaluation of dialysis access, including fluoroscopy, image documentation and report (includes injections of contrast and all necessary imaging from the arterial anastomosis and adjacent artery through entire venous outflow including the inferior or superior vena cava), radiological supervision and interpretation), 75962 (Transluminal balloon angioplasty, peripheral artery other than renal, or other visceral artery, iliac or lower extremity, radiological supervision and interpretation), and 75968 (Transluminal balloon angioplasty, each additional visceral artery, radiological supervision and interpretation). At the October 2015 CPT Editorial Panel meeting, the panel approved the creation of four new codes and deletion of 13 existing codes used to describe bundled percutaneous transluminal angioplasty services. The Open and Percutaneous Transluminal Angioplasty family of codes overlaps with the Dialysis Circuit family of codes (CPT codes 369X1–369X9), as they are both being constructed from the same set of frequently reported together codes. We reviewed these two families of codes concurrently to maintain relativity between these clinically similar procedures based upon the same collection of deleted codes. After consideration of these materials, we are proposing to accept the RUC-recommended work RVU for CPT codes 372X1, 372X2, 372X3, and 372X4.

For the clinical labor direct PE inputs, we are proposing to use the RUC-recommend inputs with several refinements. Our proposed inputs refine the recommended clinical labor time for "Prepare and position patient/monitor patient/set up IV" from 5 minutes to 3 minutes for CPT codes 372X1 and 372X3. The RUC recommendation included a written justification for additional clinical labor time beyond the standard 2 minutes for this activity, stating that the extra time was needed to move leads out of X-ray field, check that X-ray is not obstructed and that there is no risk of collision of X-ray equipment with patient. As we wrote for the same clinical labor activity in the Dialysis Circuit family, we agree that extra time may be needed for this activity as compared to the default standard of 2 minutes; however, we are assigning 1 extra minute for the additional positioning tasks, resulting in a total of 3 minutes for this task. We do not believe that 3 extra minutes would be typically needed for preparation of the X-ray. The equipment times for the angiography room (EL011) and the PACS workstation (ED050) have been refined to reflect this change in clinical labor.

We are proposing to remove the "drape, sterile, femoral" supply (SB009) and replace it with a "drape, sterile, fenestrated 16in x 29in" supply (SB011) for CPT codes 372X1 and 372X3. The two base codes out of which these new codes are being constructed, CPT codes 35471 and 35476, both made use of the SB011 fenestrated sterile drape supply, and there was no rationale provided for the switch to the SB009 femoral sterile drape in the two new codes. We are seeking comment on the use of sterile drapes for these procedures, and what rationale there is to support the use of the SB009 femoral sterile drape as typical for these new procedures.

(13) Percutaneous Biliary Procedures Bundling (CPT Codes 47531, 47532, 47533, 47534, 47535, 47536, 47537, 47538, 47539, 47540, 47541, 47542, 47543, and 47544)

This group of fourteen codes was reviewed by the RUC at the April 2015 meeting. We established interim final values for this group of codes during the CY 2016 PFS rulemaking cycle, and subsequently received updated RUC recommendations from the October 2015 meeting for the CY 2017 PFS rulemaking cycle. Our proposals for these codes incorporate both the updated RUC recommendations, as well as public comments received as part of the interim final status of these procedures.

We received several comments regarding the CMS refinements to the work values for this family of codes in the CY 2016 final rule with comment period. The relevance of many of these comments has been diminished by the new series of RUC recommendations for work values that we received as a result of the October 2015 meeting. Given that we are proposing the updated RUC-recommended work RVUs for CPT codes 47531, 47532, 47533, 47534, 47535, 47536, 47537, 47538, 47539, 47540, 47542, 47543, and 47544, we seek additional comments relative to these proposed values. We agree that the second round of physician surveys conducted for the October 2015 RUC meeting more accurately captured the work and time required to perform these procedures. The one exception is CPT code 47541; the survey times for this procedure were identical as conducted for the April and October 2015 RUC meetings, yet the RUC recommendation increased from a work RVU of 5.61 in April to a work RVU of 7.00 in October. Given that the time values for the procedure remained unchanged between the two surveys, we do not understand why the work RVU would have increased by nearly 1.50 in the intervening months. Since this code also has an identical intraservice time (60 minutes) and total time (121 minutes) as CPT code 47533, we do not agree that it should be valued at a substantially higher rate compared to a medically similar procedure within the same code family. We are therefore proposing to crosswalk the work value of CPT code 47541 to the work value of CPT code 47533, and we are proposing a work RVU of 5.63 for both procedures.

We also note that many of the codes in the Percutaneous Biliary Procedures family were previously included in Appendix G, and were valued under the assumption that moderate sedation was typically performed on the patient. As part of the initiative to pay separately for moderate sedation when it is performed, we are removing a portion of the work RVU and preservice work time from CPT codes 47532, 47533, 47534, 47535, 47536, 47538, 47539, 47540, and 47541. For example, we are proposing that CPT code 47541 undergoes a 0.25 reduction in its work RVU from 5.63 to 5.38, and a 10 minute reduction in its preservice work time from 33 minutes to 23 minutes, to reflect the work that will now be reported separately using the new moderate sedation codes. CPT codes 47542, 47533, and 47544 are also included in the moderate sedation initiative; however, as add-on codes, they are not subject to alterations in their work RVUs or work times since the moderate sedation code with work RVUs and work time (991X2) will only be billed once for each base-code and not additionally with the add-on codes. These changes are reflected in Appendix B and the work time file posted to the Web; see section II.D for more details.

For the direct PE inputs, we are proposing to remove the L051A clinical labor for "Sedate/apply anesthesia" and the L037D for "Assist Physician in Performing Procedure" for CPT codes 47531 and 47537. As we wrote in last year's final rule with comment period (80 FR 71053), we believe that this clinical labor describes activities associated with moderate sedation, and moderate sedation is not typical for these procedures. We are also proposing to refine the L037D clinical labor for "Clean room/equipment by physician staff" from 6 minutes to 3 minutes for all of the codes in this family. Three minutes is the standard for this clinical labor activity, and we continue to maintain that the need for additional clinical labor time for this cleaning activity would not be typical for these procedures.

Comment: One commenter disagreed with our refinement to replace supply item "catheter, balloon, PTA" (SD152) with supply item "catheter, balloon ureteral (Dowd)" (SD150). The commenter stated that a Dowd catheter is designed and FDA approved for use in the prostatic urethra by retrograde placement through the penile urethra, and it is not designed for use in an antegrade ureteral dilation procedure. The commenter stated that this replacement is inappropriate. The updated RUC recommendations for this family of codes also restored the balloon PTA catheter.

Response: We are proposing again to replace the recommended supply item "catheter, balloon, PTA" (SD152) with supply item "catheter, balloon ureteral (Dowd)" (SD150). We believe that the use of this ureteral balloon catheter, which is specifically designed for catheter and image guidance procedures, would be more typical than the use of a PTA balloon catheter. While we recognize that the Dowd catheter is not FDA approved, it is our understanding that the PTA balloon catheter has also not been FDA approved for use in these procedures. We are uncertain if the commenter was requesting that we should no longer include catheters that lack FDA approval in the direct PE database; this would preclude the use of most of the catheters in our direct PE database. We welcome additional comment on the use of FDA approved catheters; in the meantime, we will continue our long-standing practice of using the catheters in the direct PE database without explicit regard to FDA approval in particular procedures.

We are also proposing to remove the recommended supply item "stone basket" (SD315) from CPT code 47543 and add it to CPT code 47544. Based on the code descriptors, we believe that the stone basket was intended to be included in CPT code 47544 and was erroneously listed under CPT code 47543. We are soliciting comments from the public to help clarify this issue.

We note again that many of the codes in the Percutaneous Biliary Procedures family were previously included in Appendix G, and as part of the initiative to pay separately for moderate sedation when performed, we are removing some of the recommended direct PE inputs related to moderate sedation from CPT codes 47532, 47533, 47534, 47535, 47536, 47538, 47539, 47540, and 47541. We are removing the L051A clinical labor time for "Sedate/apply anesthesia", "Assist Physician in Performing Procedure (CS)", and "Monitor pt. following moderate sedation". We are also removing the conscious sedation pack (SA044) supply, and some or all of the equipment time for the stretcher (EF018), the mobile instrument table (EF027), the 3-channel ECG (EQ011), and the IV infusion pump (EQ032). These changes are reflected in the public use files posted to the web; see section II.D for more details.

(14) Flexible Laryngoscopy (CPT Codes 31575, 31576, 31577, 31578, 317X1, 317X2, 317X3, and 31579)

After we identified CPT codes 31575 and 31579 as potentially misvalued in (80 FR 70912–70914) the RUC referred the entire flexible laryngoscopy family of codes back to CPT for revision and the addition of several codes representing new technology within this family of services. At the May 2015 CPT meeting, the Editorial Panel added three new codes to describe laryngoscopy with ablation or destruction of lesion and therapeutic injection. Based on the survey results, the time resources involved in furnishing the procedures described by this code family experienced a significant reduction in the intraservice period, yet the recommended work RVUs were not similarly reduced. Therefore, in reviewing the recommended values for this family of codes we looked for a rationale for increased intensity and absent such rationale, propose to adjust the recommend work RVUs to account for significant changes in time.

For CPT code 31575, we disagree with the RUC-recommended work RVU of 1.00, and we are instead proposing a work RVU of 0.94. We looked at the total time ratio for CPT code 31575, which is decreasing from 28 minutes to 24 minutes, and applied this ratio of 0.86 times the current work RVU of 1.10 to derive our proposed work RVU of 0.94. We are supporting this value for CPT code 31575 through a crosswalk to CPT code 64405 (Injection, anesthetic agent; greater occipital nerve), which shares 5 minutes of intraservice time and also has a work RVU of 0.94.

We agree with the RUC that CPT code 31575 serves as the base code for the rest of the Flexible Laryngoscopy family. As a result, we are proposing to maintain the same RUC-recommended increments for the rest of the codes in this family, measuring the increments from CPT code 31575's refined work RVU of 0.94 instead of the RUC-recommended work RVU of 1.00. This means that each of the work RVUs for the codes in the rest of the family has decreased by 0.06 when compared to the RUC-recommended value. We are therefore proposing a work RVU of 1.89 for CPT code 31576, a work RVU of 2.19 for CPT code 31577, a work RVU of 2.43 for CPT code 31578, a work RVU of 3.01 for CPT code 317X1, a work RVU of 2.43 for CPT code 317X2, a work RVU of 2.43 for CPT code 317X3, and a work RVU of 1.88 for CPT code 31579.

Amongst the direct PE inputs, we are proposing to refine the clinical labor time for "Obtain vital signs" for CPT codes 31577 and 31579 from 3 minutes to 2 minutes. We believe that this extra clinical labor time is duplicative, as these codes are typically performed with a same day E/M service. Each procedure is only allotted a maximum of 5 minutes for obtaining vital signs, and since 3 minutes are already included in the E/M code, we are proposing to reduce the time to 2 minutes for these services. Similarly, we are proposing to remove the 3 minutes of clinical labor time for "Clean room/equipment by physician staff" from CPT codes 31575, 31577, and 31579. These procedures are typically reported with a same day E/M service, making the clinical labor minutes for cleaning the room in these procedure codes duplicative of the time already included in the E/M codes.

For CPT code 317X1, we are proposing to remove the "laser tip, diffuser fiber" supply (SF030) and replace it with the "laser tip, bare (single use)" supply (SF029) already present in our direct PE database. We believe that the invoice for SF030 submitted with the RUC recommendation is not current enough to establish a new price for this supply; as a result, we are substituting the SF029 supply for this input. We welcome the submission of new invoices to accurately price the diffuser fiber with laser tip.

We are also proposing to make significant changes to the prices of several of the supplies and equipment related to Flexible Laryngoscopy, as well as to the prices of scopes more broadly. We are proposing to set the price of the disposable biopsy forceps supply (SD318) at $26.84, based on the submission of an invoice with a price of $536.81 for a unit size of 20. In our search for additional information regarding scope inputs, we obtained a quote from a vendor listing the current price for several equipment items related to the use of scopes. Since we believe that the prices in vendor quotes would typically be equal to or higher than prices actually paid by practitioners, we are updating the prices in our direct PE database to reflect this new information. As part of this process, we are proposing to increase the price of the "light source, xenon" (EQ167) from $6,723.33 to $7,000 to reflect current pricing information. We are also proposing to adjust the price of the "fiberscope, flexible, rhinolaryngoscopy" (ES020) from $6,301.93 to $4,250.00.

In accordance with the wider proposal that we are making involving the use of scope equipment, we are proposing to separate the scopes used in these procedures from the scope video systems. In the course of researching different kinds of scopes, we obtained vendor pricing for two different types of scopes used in these procedures. We are proposing to price the "rhinolaryngoscope, flexible, video, non-channeled" (ES063) at $8,000 and the "rhinolaryngoscope, flexible, video, channeled" (ES064) at $9,000 in accordance with our vendor quotes. We are proposing to use the non-channeled scope for CPT codes 31575, 31579, and 317X3 and the channeled scope for CPT codes 31576, 31577, 31578, 317X1, and 317X2 in accordance with the RUC-recommended video systems that stipulated channeled versus non-channeled scope procedures.

We believe that the "Video-flexible laryngoscope system" listed in the recommendations is not a new form of equipment, but rather constitutes a version of the existing "video system, endoscopy" equipment (ES031). We are not adding a new equipment item to our direct PE database; instead, we are proposing to use the submitted invoices to update the price of the ES031 endoscopy video system. As the equipment code for ES031 indicates, we are proposing to define the endoscopy video system as containing a processor, digital capture, monitor, printer, and cart. We are proposing to price ES031 at $15,045.00; this reflects a price of $2,000.00 for the monitor, $9,000.00 for the processor, $1,750.00 for the cart, and $2,295.00 for the printer. These prices were obtained from our vendor invoice, with the exception of the printer, which is a crosswalk to the "video printer, color (Sony medical grade)" equipment (ED036).

We do not agree that there is a need for multiple different video systems for this collection of Flexible Laryngoscopy codes based on our understanding of the clinical differences among the codes. In keeping with this understanding, we are proposing to use the same existing "video system, endoscopy" equipment (ES031) for the remaining codes in the family that included RUC recommendations for new equipment items named "Video-flexible channeled laryngoscope system" and "Video-flexible laryngoscope stroboscopy system." For CPT codes 31576, 31577, 31578, 317X1, and 317X2, we are proposing to replace the Video-flexible channeled laryngoscope system with the existing endoscopy video system (ES031) along with a channeled flexible video rhinolaryngoscope (ES064). For CPT code 31579, we are proposing to rename the RUC-recommended "Video-flexible laryngoscope stroboscopy system" to the shortened "stroboscopy system" (ES065) and assign it a price of $19,100.00. This reflects the price of the StrobeLED Stroboscopy system included on the submitted invoice. We are proposing to treat the stroboscopy system as a scope accessory, which will be included along with the "video system, endoscopy" equipment (ES031) and the "rhinolaryngoscope, flexible, video, non-channeled" (ES063) for CPT code 31579. When the price of the scope, the scope video system, and the stroboscopy system are summed together, the total proposed equipment price is $42,145.00.

We are proposing to refine the recommended equipment times for several equipment items to conform to changes in clinical labor time. These are: The fiberoptic headlight (EQ170), the suction and pressure cabinet (EQ234), the reclining exam chair with headrest (EF008), and the basic instrument pack (EQ137). We are proposing to use the standard equipment time formula for scope accessories for the endoscopy video system (ES031) and the stroboscopy scope accessory system (ES065). We are also proposing to refine the equipment time for the channeled and non-channeled flexible video rhinolaryngoscopes to use the standard equipment time formula for scopes. For this latter pair of two new equipment items, this proposal results in small increases to their respective equipment times.

(15) Laryngoplasty (CPT Codes 31580, 31584, 31587, and 315X1–315X6)

CPT code 31588 (Laryngoplasty, not otherwise specified (*e.g.*, for burns, reconstruction after partial laryngectomy) was identified as potentially misvalued based on the RUC's 90-Day Global Post-Operative Visits screen. When this code family was reviewed by the RUC, it was determined that some codes in the family required revision to reflect the typical patient before a survey could be conducted and the code family was referred to the CPT Editorial Panel for revision. At the October 2015 CPT Editorial Panel meeting, the CPT Editorial Panel approved the creation of six new codes, revision of three codes, and deletion of three codes. For CPT codes 31580, 31587, 315X1, 315X2, 315X3, 315X4, and 315X6, CMS is proposing the RUC-recommended work RVUs.

For CPT code 31584, the RUC recommended a work RVU of 20.00. We believe that the 25th percentile of the survey, which is a work RVU of 17.58, better represents the time and intensity involved with furnishing this service based on a comparison with and assessment of the overall intensity of other codes with similar instraservice and total time. This value is also supported by a crosswalk code of CPT code 42844 (Radical resection of tonsil, tonsillar pillars, and/or retromolar trigone; closure with local flap (*e.g.*, tongue, buccal)), which has identical intraservice time and identical total time. Therefore, we are proposing a work value of 17.58 RVUs for CPT code 31584.

For CPT code 315X5, the RUC recommended a work value of 15.60 RVUs. We believe that the 25th percentile of the survey, which is a work RVU of 13.56, better represents the time and intensity involved with furnishing this service based on a comparison of the overall intensity of other codes with similar instraservice and total time. The 25th percentile of the survey is additionally bracketed by two crosswalk codes that we estimate have slightly lower and slighter higher overall intensities, CPT code 36819

(Arteriovenous anastomosis, open; by upper arm basilic vein transposition), which has a work RVU of 13.29, and CPT code 49654 (Laparoscopy, surgical, repair, incisional hernia (includes mesh insertion, when performed); reducible), which has a work RVU of 13.76; both of these codes have identical intraservice time and similar total time. Therefore, we are proposing a work RVU of 13.56 for CPT code 315X5.

Additionally, the RUC forwarded invoices provided by a medical specialty society for the video-flexible laryngoscope system used in these services. As discussed in section II.A of this proposed rule, we have proposed changes to the items included in equipment item ES031 (video system, endoscopy). Consistent with those proposed changes, we are proposing to add a Nasolaryngoscope, non-channeled, to the list of equipment items used for CPT codes 31580, 31584, 31587, and 315X1–315X6, along with the modified equipment item ES031.

(16) Mechanochemical Vein Ablation (MOCA) (CPT Codes 364X1 and 364X2)

At the October 2015 CPT meeting, the CPT Editorial Panel established two Category I codes for reporting venous mechanochemical ablation, CPT codes 364X1 and 364X2. We are proposing the RUC-recommended work RVU of 3.50 for CPT code 364X1. For CPT code 364X2 we believe that the RUC-recommended work RVU of 2.25 does not accurately reflect the typical work involved in furnishing this procedure. The specialty society survey recommended that this add-on code has half the work of the base code, CPT code 364X1. This value is supported by the ratio between work and time in the key reference service, CPT code 36476 (Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, radiofrequency; second and subsequent veins treated in a single extremity, each through separate access sites (List separately in addition to code for primary procedure)). Therefore, we are proposing a work RVU of 1.75 for CPT code 364X2.

The RUC-recommended direct practice expense inputs for CPT codes 364X1 and 364X2 included inputs for an ultrasound room (EL015). Based on the clinical nature of these procedures, we do not believe that an ultrasound room would typically be used to furnish these procedures. We are proposing to remove inputs for the ultrasound room and put in a portable ultrasound (EQ250), power table (EF031), and light (EF014). The RUC also recommended that the ultrasound machine be allocated clinical staff time based on the PACS workstation formula. We do not believe that an ultrasound machine would be used like a PACS workstation, as images are generated and reviewed in real time. Therefore, we are proposing to remove all inputs associated with the PACS workstation.

(17) Esophageal Sphincter Augmentation (CPT Codes 432X1 and 432X2)

In October 2015, the CPT Editorial Panel created two new codes to describe laparoscopic implantation and removal of a magnetic bead sphincter augmentation device used for treatment of gastroesophageal reflux disease (GERD). The RUC noted that the specialty societies conducted a targeted survey of the 145 physicians who have been trained to furnish these services and who are the only physicians who have performed these procedures. They noted that only 18 non-conflicted survey responses were received despite efforts to follow up and that nine physicians had no experience in the past 12 months with the procedure. The RUC agreed with the specialty society that the expertise of those responding was sufficient to consider the survey, however, neither entity used the survey results as the as the primary basis for their recommended value.

For CPT code 432X1, the RUC recommended a work RVU of 10.13. We compared this code to CPT code 43180 (Esophagoscopy, rigid, transoral with diverticulectomy of hypopharynx or cervical esophagus (*e.g.*, Zenker's diverticulum), with cricopharyngeal myotomy, includes use of telescope or operating microscope and repair, when performed), which has a work RVU of 9.03 and has identical intraservice time and similar total time. We believe the overall intensity of these procedures is similar, therefore, we are proposing a work RVU of 9.03 for CPT code 432X1.

For CPT code 432X2, the RUC recommended a work RVU of 10.47. To value this code, we used the increment between the RUC-recommended work RVU for this code and CPT code 432X1 (0.34 RVUs) to develop our proposed work RVU of 9.37 for CPT code 432X2.

(18) Electromyography Studies (CPT Code 51784)

We identified CPT code 51784 as potentially misvalued through a screen of high expenditure by specialty. This family also includes CPT code 51785 (Needle electromyography studies (EMG) of anal or urethral sphincter, any technique) but was not included in this survey. Both services have 0-day global periods. The RUC recommended a work RVU of 0.75 for CPT code 51784. We believe that this service is more accurately valued without a global period, since that is more consistent with other diagnostic services, and specifically, with all the other diagnostic electromyography services. We are proposing a change to the global period from 0-day to no global period, and we are proposing the RUC-recommended work RVU of 0.75 for CY 2017. We are also proposing to change the global period for CPT code 51785 from 0-day to no global period, to be consistent with 51784. Additionally, we are proposing to add CPT code 51785 to the list of potentially misvalued codes to update the value of the service considering the change in global period, and to maintain consistency with 51784.

(19) Cystourethroscopy (CPT Code 52000)

In the CY 2016 PFS final rule with comment period, CMS identified CPT code 52000 through the screen for high expenditure services by specialty screen. The RUC-recommended work RVUs of 1.75 for CPT code 52000 is larger than the work RVUs for all 0-day global codes with 10 minutes of intraservice time and we do not believe that the overall intensity of this service is greater than all of the other codes. Instead, we believe the overall work compares for this code compares favorably to CPT code 58100 (Endometrial sampling (biopsy) with or without endocervical sampling (biopsy), without cervical dilation, any method (separate procedure)), which has a work RVU of 1.53, and has identical intraservice time and similar total time. Therefore, we are using a direct crosswalk to CPT code 58100 and are proposing a work RVU of 1.53 for CPT code 52000.

(20) Biopsy of Prostate (CPT Code 55700)

In the CY 2016 PFS final rule with comment period, CMS identified CPT code 55700 as potentially misvalued based on the high expenditure by specialty screen.

The RUC subsequently reviewed this code for physician work and practice expense and recommended a work RVU of 2.50 based on the 25th percentile of the survey. We believe the RUC-recommended work RVU overestimates the work involved in furnishing this service given the reduction in total service time; specifically, the reduction in preservice and postservice times. The RUC recommendation also appears overvalued when compared to similar 0-day global services with 15 minutes of intraservice time and comparable total times. To develop a proposed work RVU, we crosswalked the work RVUs for this code from CPT code 69801 (Labyrinthotomy, with perfusion of vestibuloactive drug(s), transcanal), noting similar levels of intensity, similar total times, and identical intraservice times. Therefore, we are proposing a work RVU of 2.06 for CPT code 55700.

As part of the recommended direct PE inputs for CPT code 55700, the RUC recommended inclusion of a new equipment item, Biopsy Guide, but we have not received any invoices to price this item. Given our longstanding difficulties in acquiring accurate pricing information for equipment items, we are seeking invoices and public comment for pricing this equipment prior to adding this new equipment item code.

(21) Hysteroscopy (CPT Codes 58555–58563)

In the CY 2016 PFS proposed rule, we proposed CPT code 58558 as a potentially misvalued code based on the screen for high expenditure by specialty screen. This code was reviewed at the January 2016 RUC meeting and CPT codes 58559–58563 were included in the review as part of the family.

For CPT code 58555, the RUC recommended a work RVU of 3.07. We believe that the 25th percentile of the survey, a work RVU of 2.65, more accurately reflects the resources involved in furnishing this service. This value is bracketed by two crosswalk codes, CPT code 43191 (Esophagoscopy, rigid, transoral; diagnostic, including collection of specimen(s) by brushing or washing when performed (separate procedure)), which has a work RVU of 2.49, and CPT code 31295 (Nasal/sinus endoscopy, surgical; with dilation of maxillary sinus ostium (*e.g.*, balloon dilation), transnasal or via canine fossa), which has a work RVU of 2.70. Compared with CPT code 58555, CPT codes 43191 and 31295 have identical intraservice times and similar total times. Therefore, we are proposing a work RVU of 2.65 for CPT code 58555.

For CPT code 58558, the RUC recommended a work RVU of 4.37. However, we believe that a direct crosswalk from CPT code 36221 (Non-selective catheter placement, thoracic aorta, with angiography of the extracranial carotid, vertebral, and/or intracranial vessels, unilateral or bilateral, and all associated radiological supervision and interpretation, includes angiography of the cervicocerebral arch, when performed), which has a work RVU of 4.17, and which has identical intraservice time and very similar total time, more accurately reflects the time and intensity of furnishing this service. This value is additionally supported by using an increment between this code and the base code for this family, CPT code 58555. The increment between the RUC-recommended values for these two codes is 1.3. That increment added to the proposed work RVU of 2.65 for the base code, CPT code 58555, results in a work RVU of 3.95. Therefore, we are proposing a work value of 4.17 RVUs for CPT code 58558.

For CPT code 58559, the RUC recommended a work RVU of 5.54. However, we believe that a direct crosswalk of the work RVUs for CPT code 52315 (Cystourethroscopy, with removal of foreign body, calculus, or ureteral stent from urethra or bladder (separate procedure); complicated), which has a work RVU of 5.20 and which has a similar (slightly higher) intraservice time and similar total time as compared with CPT code 58589 more accurately reflects the time and intensity of furnishing this service. This value is additionally supported by using an increment between CPT code 58559 and the base code for this family, CPT code 58555. The increment between the RUC recommended values for the two codes is 2.47. That increment added to the proposed value for the base code, CPT code 58555 (2.65), results in a work RVU of 5.12. Therefore, we are proposing a work RVU of 5.20 for CPT code 58559.

For CPT code 58560, the RUC recommended a work RVU of 6.15. However, we believe that a direct crosswalk of the work RVUs for CPT code 52351 (Cystourethroscopy, with ureteroscopy and/or pyeloscopy; diagnostic), which has a work RVU of 5.75 and which has more intraservice time and very similar total time, more accurately reflects the time and intensity of furnishing this service. This value is additionally supported by using an increment between CPT code 58560 and the base code for this family, CPT code 58555. The increment between the RUC recommended values for the two codes is 3.08. That increment added to the proposed value for the base code, CPT code 58555 (2.65), results in a work RVU of 5.73. Therefore, we are proposing a work RVU of 5.75 for CPT code 58560.

For CPT code 58561, the RUC recommended a work RVU of 7.00. However, we believe that a direct crosswalk of the work RVUs for CPT code 35475 (Transluminal balloon angioplasty, percutaneous; brachiocephalic trunk or branches, each vessel), which has a work RVU of 6.60 and which has similar intraservice and total times, more accurately reflects the time and intensity of furnishing this service. This value is additionally supported by using an increment between CPT code 58561 and the base code for this family, CPT code 58555. The increment between the RUC recommended values for the two codes is 3.93. That increment added to the proposed value for the base code, CPT code 58555 (2.65), results in a work RVU of 6.58. Therefore, we are proposing a work RVU of 6.60 for CPT code 58561.

For CPT code 58562, the RUC recommended a work RVU of 4.17. However, we believe that a direct crosswalk of the work RVUs for CPT code 15277 (Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area greater than or equal to 100 sq cm; first 100 sq cm wound surface area, or 1% of body area of infants and children), which has a work RVU of 4.00 and which has identical intraservice time and similar total time, more accurately reflects the time and intensity of furnishing this service. The RUC also used this code as one of its supporting codes for its recommendation. This value is additionally supported by using an increment between CPT code 58562 and the base code for this family, CPT code 58555. The increment between the RUC recommended values for the two codes is 1.10. That increment added to the proposed value for the base code, CPT code 58555 (2.65), results in a work RVU of 3.75. Therefore, we are proposing a work RVU of 4.00 for CPT code 58562.

For CPT code 58563, the RUC recommended a work RVU of 4.62. However, we believe that a direct crosswalk of the work RVUs for CPT code 33962 (Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; reposition peripheral (arterial and/or venous) cannula(e), open, 6 years and older (includes fluoroscopic guidance, when performed)), which has a work RVU of 4.47 and which has identical intraservice time and similar total time, more accurately reflects the resources involved in furnishing this service. This value is additionally supported by using an increment between CPT code 58563 and the base code for this family, CPT code 58555. The increment between the RUC recommended values for the two codes is 1.55. That increment added to the proposed value for the base code, CPT code 58555 (2.65), results in a work RVU of 4.20. We note that CPT code 58563 has the same instraservice time and the same total time as CPT code 58558; however, we agree that the intensity would be slightly higher for this service. Therefore, we are proposing a work RVU of 4.47 for CPT code 58562.

The RUC submitted invoices for two new equipment items used in furnishing CPT code 58558, the Hysteroscopic Fluid Management System and the Hysteroscopic Resection System. We are proposing to use these invoice prices for the Hysteroscopic Fluid Management System, which totaled $14,698.38. The Hysteroscopic Resection System included the price of the hysteroscope as well as other items necessary for tissue removal. However, we generally price endoscopes separately and not as a part of a system. In order to maintain consistency, we are proposing not to include the hysteroscope from the Resection System. Instead, we are proposing to update the equipment item "endoscope, rigid, hysteroscopy" (ES009) with the invoice price, $6,207.50. We are not proposing to include the sterilization tray from the Hysteroscopic Resection System because we believe this tray has generally been characterized as an indirect expense. For the Hysteroscopic Resection System, we are proposing to include the Hysteroscopic tissue remover ($18,375), the sheath ($1,097.25), and the calibration device ($300), and creating a new equipment item code, priced at $19,857.50 in the proposed direct PE input database. We did not propose to include the calibration device since the submitted price was not documented with a paid invoice.

(22) Epidural Injections (CPT Codes 623X5, 623X6, 623X7, 623X8, 623X9, 62X10, 62X11, and 62X12)

We are proposing the RUC-recommended work RVU for all eight of the codes in this family.

We are proposing to remove the 10–12ml syringes (SC051) and the RK epidural needle (SC038) from all eight of the codes in this family. These supplies are duplicative, as they are included in the epidural tray (SA064). As an alternative, we could remove the epidural tray and replace it with the individual supply components used in each procedure; we are seeking public comment on either the inclusion of the epidural tray or its individual components for this family of codes.

(23) Endoscopic Decompression of Spinal Cord (CPT code 630X1)

For CY 2016, the CPT Editorial Panel created CPT code 630X1 to describe the endoscopic decompression of neural elements. The RUC recommended a work RVU of 10.47 based on a crosswalk to CPT code 47562 (Laparoscopy, surgical; cholecystectomy) with a higher intraservice time than reflected in the survey data. Since we believe CPT codes 630X1 and 47562 are similar in intensity, we believe using the same work RVU as the crosswalk code overestimates the work involved in furnishing CPT code 630X1. Reference CPT code 49507 (Repair initial inguinal hernia, age 5 years or older; incarcerated or strangulated) has a work RVU of 9.09 and has similar intensity and an identical intraservice time compared to CPT code 630X1. Therefore, we are proposing a work RVU of 9.09 for CPT code 630X1.

(24) Retinal Detachment Repair (CPT Codes 67101 and 67105)

For CY 2015, the CPT Editorial Panel made several changes to CPT codes 67101 and 67105. These changes include revising the code descriptors to exclude "diathermy" and "with or without drainage of subretinal fluid" and removing the reference to "1 or more sessions". The recommended global period has also changed from 90 days to 10 days.

For CPT code 67101 we propose the RUC recommendation of 3.50 work RVUs, which was based on the 25th percentile of the survey. For CPT code 67105, the RUC recommended a work RVU of 3.84 based on the 25th percentile of the survey. The RUC also stated that CPT code 67105 was a more intense procedure, and therefore, should have a higher work RVU than CPT code 67101. Currently, CPT code 67101 has a higher work RVU than CPT code 67105 and according to the surveys the intraservice and total times remain higher for CPT code 67101. It was not clearly explained and we do not understand why the RUC believes that CPT code 67105 is more work than CPT code 67101. Therefore we are not proposing the RUC-recommended work value of 3.50 for CPT code 67105. We do not find evidence that CPT code 67105 is more intense than CPT code 67101 and accordingly propose a new value for CPT code 67105. To value CPT code 67105 we used the RVU ratio between 67101 and 67105. We divided the current work RVU of CPT code 67105 (8.53), by the current work RVU of CPT code 67101 (8.80) and multiplied the quotient by the RUC-recommended work RVU for CPT code 67101 (3.50) to arrive at a product of 3.39 work RVUs.

Therefore, for CY 2017 we are proposing a work RVU of 3.39 for CPT code 67105.

(25) Abdominal Aortic Ultrasound Screening (CPT Code 767X1)

For CY 2017, the CPT Editorial Panel created a new code, CPT 767X1, to describe abdominal aortic ultrasound screening, currently described by HCPCS G-code G0389. The specialties that surveyed CPT code 767X1 for the RUC were vascular surgery and radiology, and the direct practice expense inputs recommended by the RUC included an ultrasound room. Based on an analysis of Medicare claims data, the dominant specialties furnishing the service are family practice and internal medicine. We believe that these specialties may more typically use a portable ultrasound device rather than an ultrasound room. Therefore, we are proposing to accept the RUC-recommended work value of 0.55, and the RUC-recommended PE inputs for this service, but we are seeking comment regarding whether or not it would be more accurate to substitute a portable ultrasound device or possibly a hand-held device for an ultrasound room for CPT code 767X1. We note that while the phase-in of significant reductions in RVUs ordinarily would not apply to new codes, we believe that it would be appropriate to consider this change from a G-code to a CPT code to be fundamentally similar to an editorial coding change since the service is not described differently, and therefore, we propose to apply the phase-in to this service by comparing the previous value of the G-code to the value for the new CPT code.

(26) Fluoroscopic Guidance (CPT Codes 77001, 77002, and 77003)

In the CY 2015 PFS final rule with comment period, CMS indicated that while CPT codes 77002 and 77003 had been previously classified as stand-alone codes without global periods, we believe their vignettes and CPT Manual parentheticals are consistent with an add-on code as has been established for CPT code 77001. Therefore, the global periods for CPT codes 77002 and 77003 now reflect an add-on code global period with modifications to the vignettes and parentheticals.

For CPT code 77001, we are proposing the RUC-recommended work RVU of 0.38. The RUC-recommended work RVUs for CPT codes 77002 and 77003 do not appear to account for the significant decrease in total times for these codes relative to the current total times. We note that these three codes describe remarkably similar services and have identical intraservice and total times. Based on the identical times and notable similarity for all three of these codes, we are proposing a work RVU of 0.38 for all three codes.

(27) Radiation Treatment Devices (CPT Codes 77332, 77333, and 77334)

We identified CPT codes 77332, 77333, and 77334 through the high expenditures by specialty screen. These services represent an incremental increase of complexity from the simple to the intermediate to the complex in design of radiation treatment devices. The RUC recommended no change from the current work RVUs for these codes, which are currently 0.54 for CPT code 77332, 0.84 for CPT code 77333 and 1.24 for CPT code 77334. We believe the recommended work RVUs overstate the work involved in furnishing these services, as they do not sufficiently reflect the degree to which the RUC concurrently recommended a decrease in intraservice or total time. For CPT code 77332, we believe the RUC recommendation to maintain its current value despite a 34 percent decrease in total time appears to ignore the change in time. Therefore, we are proposing a value for this code based on a crosswalk from the value from CPT code 93287 (Peri-procedural device evaluation (in person) and programming of device system parameters before or after a surgery, procedure, or test with analysis, review and report by a physician or other qualified health care professional; single, dual, or multiple lead implantable defibrillator system)), due to its identical intraservice time, similar total time, and similar level of intensity. We are therefore proposing a work RVU of 0.45 for CPT code 77332. We are further supporting this valuation with HCPAC code 97760 (Orthotic(s) management and training (including assessment and fitting when not otherwise reported) upper extremity(s), lower extremity(s) and/or trunk, each 15 minutes), which has similar physician time and intensity measurements and a work RVU of 0.45. As these codes are designed to reflect an incremental increase in work value from simple, to intermediate, and complex device designs, we used an incremental difference methodology to value CPT codes 77333 and 77334. We are proposing a work RVU of 0.75 for CPT code 77333, maintaining its recommended increment from CPT code 77332, For CPT code 77334, we are proposing a work RVU of 1.15 which maintains its increment from CPT code 77332.

(28) Special Radiation Treatment (CPT Code 77470)

We identified CPT code 77470 through the high expenditure charges by specialty. We are proposing the RUC-recommended work RVU of 2.03. However, we believe the description of service and vignette describe different and unrelated treatments being performed by the physician and clinical staff for a typical patient, and this presents a disparity between the work RVUs and PE RVUs. We seek public comment on information that would clarify this apparent disparity to help determine appropriate PE inputs. In addition, we seek comment to determine if creating two G-codes, one which describes the work portion of this service, and one which describes the PE portion, may be a potentially more accurate method of valuing and paying for the service or services described by this code.

(29) Flow Cytometry Interpretation (CPT Codes 88184, 88185, 88187, 88188, and 88189)

The Flow Cytometry Interpretation family of codes is split into a pair of codes used to describe the technical component of flow cytometry (CPT codes 88184 and 88185), which do not have a work component, and a trio of codes (CPT codes 88187, 88188, and 88189) which do not have direct practice expense inputs, as they are professional component only services. CPT codes 88184 and 88185 were reviewed by the RUC in April 2014, and their CMS refined values were included in the CY 2016 PFS final rule with comment period. The full family of codes was reviewed again at the January 2016 RUC meeting, and new recommendations were submitted to CMS as part of the CY 2017 PFS rulemaking cycle.

We are proposing the RUC-recommended work RVU of 0.74 for CPT code 88187, and the RUC-recommended work RVU of 1.70 for CPT code 88189. For CPT code 88188, we are proposing a work RVU of 1.20 instead of the RUC-recommended work RVU of 1.40. We arrived at this value by noticing that there were no comparable codes with no global period in the RUC database with intraservice time and total time of 30 minutes that had a work RVU higher than 1.20. The RUC-recommended work RVU of 1.40 would go beyond the current maximum value and establish a new high, which is not consistent with our estimation of the overall intensity of this service relative to the others. As a result, we believe it is more accurate to crosswalk CPT code 88188 to the work value of the code with the current highest value, which is CPT code 88120 (Cytopathology, in situ hybridization (for example, FISH), urinary tract specimen with morphometric analysis, 3–5 molecular probes) at a work RVU of 1.20. We believe that CPT code 88120 is crosswalk comparable code since it shares the identical intraservice time and total time of 30 minutes with CPT code 88188.

We also noted that the survey increment between CPT codes 88187 and 88188 at the RUC-recommended 25th percentile was 0.40 (between work RVUs of 1.00 and 1.40), and this increment of 0.40 when added to CPT code 88187's work RVU of 0.74 would arrive at a value of 1.14. In addition, the total time for CPT code 88188 decreases from 43 minutes to 30 minutes, which is a ratio of 0.70, and when this time ratio is multiplied by CPT code 88188's previous work value of 1.69, the result would be a new work RVU of 1.18. With this information in mind, we are proposing a work RVU of 1.20 for CPT code 88188 as a result of a direct crosswalk to CPT code 88120.

For CPT codes 88184 and 88185, which describe the technical component of flow cytometry, we are proposing to use the RUC-recommended inputs with a series of refinements. However, we believe that the coding for these two procedures may inhibit accurate valuation. CPT code 88184 describes the first marker for flow cytometry, while CPT code 88185 is an add-on code that describes each additional marker. We believe that it may be more accurate to have a single CPT code that describes the technical component of flow cytometry on a per patient case basis, as these two procedures are always performed together and it is difficult to determine the clinical labor, supplies, and equipment used in the typical case under the current coding structure. We are soliciting comments regarding the public interest in consolidating these two procedures into a single code used to describe the technical component of flow cytometry.

Absent such a change in coding, we are proposing to refine the clinical labor time for "Instrument start-up, quality control functions, calibration, centrifugation, maintaining specimen tracking, logs and labeling" from 15 minutes to 13 minutes for CPT code 88184. We maintain that 13 minutes for this activity, which is the current time value, would be typical for the procedure, as CPT code 88182 also uses 13 minutes for the identical clinical labor task. We are also proposing to refine the L054A clinical labor for

"Load specimen into flow cytometer, run specimen, monitor data acquisition, and data modeling, and unload flow cytometer" from 10 minutes to 7 minutes using the same rationale, a comparison to CPT code 88182.

We are proposing to maintain the clinical labor for "Print out histograms, assemble materials with paperwork to pathologists Review histograms and gating with pathologist" for CPT code 88184 at 2 minutes, as opposed to the RUC-recommended 5 minutes. A clinical labor time of 2 minutes is standard for this activity; we disagree with the RUC rationale that reviewing histograms and gating with the pathologist in this procedure is not similar to other codes. We also note that the review of histograms with a pathologist is not even described by CPT code 88184, which again refers to the technical component of flow cytometry, not the professional component. We are also proposing to refine the L033A clinical labor time for "Clean room/equipment following procedure" from 2 minutes to 1 minute for CPT code 88184. We have established 1 minute in previous rulemaking (80 FR 70902) as the standard time for this clinical labor activity in the laboratory setting.

We are proposing to maintain our removal of the clinical labor time for "Enter data into laboratory information system, multiparameter analyses and field data entry, complete quality assurance documentation" for both CPT code 88182 and CPT code 88184. As we stated in last year's final rule with comment period (80 FR 70979), we have not recognized the laboratory information system as an equipment item that can be allocated to an individual service. We continue to believe that this is a form of indirect PE, and therefore, we do not recognize the laboratory information system as a direct PE input, and we not consider this task as typically performed by clinical labor on a per-service basis.

We are proposing to maintain the quantity of the "lysing reagent" supply (SL089) at 2 ml for CPT code 88185, as opposed to the RUC-recommended quantity of 3 ml. In our discussions with pathology specialists who perform flow cytometry, we were informed that the use of 50–55 ml of the lysing reagent would be typical for an entire patient case. The RUC recommendation similarly suggested a quantity of 46 ml or 48 ml per patient case. We were also told that the most typical number of markers used for flow cytometry is 24, consisting of 1 service of CPT code 88184 and 23 services of CPT code 88185. An investigation of our claims data confirmed this information, indicating that 24 markers is the most frequent per patient case for flow cytometry, and the use of more than 20 markers is typical. We believe that this data supports our refinement of the lysing reagent from a quantity of 3 ml to a quantity of 2 ml for CPT code 88185, which is also the current value for the procedure and the RUC-recommended value from the previous set of recommendations. For the typical case of 24 markers, our value would produce a total lysing reagent quantity of 51 ml (5 ml from the single service of CPT code 88184 and 46 ml from the 23 services of CPT code 88185), which matches with the amount required for a total per patient case. If we were to adopt the RUC recommendation, the total lysing reagent quantity would be 74 ml, which is well in excess of what we believe to be typical for these procedures.

We are also proposing to refine the quantity of the "antibody, flow cytometry" supply (SL186) from quantity 1.6 to quantity 1, which is also the current value for the supply and the RUC-recommended value from the previous set of recommendations. We do not agree that more than one antibody would be typically used for each marker. We are reaffirming the previous RUC recommendation, and maintaining the current quantity of 1 antibody for each marker.

We are not proposing the recommended additional time for the "printer, dye sublimation (photo, color)" equipment (ED031). We are proposing to maintain the equipment time at 2 minutes for CPT code 88184, and at 1 minute for CPT code 88185. As we stated in the CY 2016 PFS final rule with comment period (80 FR 70979), we are proposing to assign equipment time for the dye sublimation printer to match the clinical labor time for "Print out histograms, assemble materials with paperwork to pathologists." We do not believe that it would be typical for the printer to be in use longer than it takes to accomplish this clinical labor task.

(30) Mammography—Computer Aided Detection Bundling (CPT Codes 770X1, 770X2 and 770X3)

Section 104 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554) required us to create separate codes with higher payment amounts for digital mammography compared to film mammography, which was the technology considered to be typical at the time. In addition, the statute required additional payment to be made when computer-aided detection (CAD) was used.

In CY 2002, we began valuing digital mammography services using three G-codes, G0202, G0204, and G0206 to describe screening mammography, unilateral diagnostic mammography, and bilateral diagnostic mammography, respectively. CMS implemented the requirements of BIPA section 104(d)(1), which applied to tests furnished in 2001, by using the work RVUs of the parallel CPT codes, but establishing a fixed PE RVU rather than using PE RVUs developed under the standard PE methodology. The fixed amount of PE RVUs for these codes has generally remained unchanged since implementation of the G-codes that specifically described digital imaging.

Most mammography services under Medicare have since been billed with these G-codes when digital mammography was used, and with CPT codes 77055, 77056, and 77057 when film mammography was used. The use of CAD has been reported with CPT codes 77051 and 77052. For CY 2017, the CPT Editorial Panel deleted CPT codes 77051, 77052, 77055, 77056, 77057 and created three new CPT codes, 770X1, 770X2, and 770X3, to describe mammography services bundled with CAD. For CY 2017, the RUC recommended a work RVU of 0.81 for CPT code 770X1, a work RVU of 1.00 for CPT code 770X2, and a work RVU of 0.76 for CPT code 770X3, as well as new PE inputs for use in developing resource-based PE RVUs based on our standard methodologies. The RUC has recommended these inputs and only one medical specialty society has provided us with a set of single invoices to price the equipment used in furnishing these services.

We have reviewed these coding changes and recommended changes to valuation for CY 2017. The revised CPT coding mitigates the need for both separate G-codes and the CAD add-on codes. Based upon these coding changes and the recommended input values, overall Medicare payment for mammography services would be drastically reduced. This is especially the case for the technical component of these services, which could possibly be reduced up to 50 percent relative to the PE RVUs currently used for payment for these services.

Based on our initial review of the recommended inputs for the new codes, we believe that these changes would likely result in values more closely related to the relative resources involved in furnishing these services. However, we recognize that these services, particularly the preventive screenings, are of particular importance to the Medicare program and the health of the Medicare beneficiaries. We are concerned that making drastic changes in coding and payment for these services could be disruptive in ways that could affect beneficiary access to necessary services. We also recognize that unlike almost any other high-volume PFS service, the RVUs used for payment for many years have not been developed through the generally applicable PFS methodologies, and instead reflect the statutory directive under section 104 of the BIPA. Similarly, we recognize that the changes in both coding and valuation are significant changes for those who provide these services. Therefore, instead of proposing to simultaneously adopt the revised CPT coding and drastic reductions in overall payment rates, we believe it is advisable to adopt the new coding, including the elimination of separate billing for CAD, for CY 2017 without proposing immediate implementation of the recommended resource inputs. We anticipate that we will consider the recommended inputs, including the pricing of the required equipment, as carefully as possible prior to proposing revised PE values through subsequent rulemaking.

Therefore, for CPT codes 770X1, 770X2, and 770X3, we are proposing to accept the RUC-recommended work RVUs, but to crosswalk the PE RVUs for the technical component of the current corresponding G-codes, as we seek further pricing information for these equipment items.

In addition to seeking comment on this proposal, we are also seeking comment on rates for these services in the commercial market to help us understand the potential impacts of any future proposed revisions to PFS payment rates.

Finally, we note that by adopting the new coding for CY 2017, any subsequent significant reduction in RVUs (greater than 20 percent) for the codes would be subject to the statutory phase-in under section 1848(c)(7).

To help us examine the resource inputs for these services, we are seeking public comment on the list of items recommended as equipment inputs for mammography services. We also invite commenters to provide any invoices that would help with future pricing of these items.

TABLE 17—RECOMMENDED EQUIPMENT ITEMS FOR MAMMOGRAPHY SERVICES

#	Item description	Quantity	Purpose
1	2D Selenia Dimensions Mammography System.	1	Mammography unit and in-room console itself.
2	Mammo Accreditation Phantom	1	Required for MQSA. The phantom is currently valued into the existing mammography room.
3	Phantom Case	1	Protects expensive required phantom from damage.
4	Paddle Storage Rack	3	It requires 3 racks to hold and prevent damage to all of the paddles that are part of the typical standard mammography system.
5	Needle Localization Kit	1	Needed for a full functioning mammography room. Allows for the performance of needle localizations. Input is not separately in the PE for the mammography guided procedure codes, 19281–19282, as a fully functioning mammography room is needed for those procedures.
6	Advanced Workflow Manager System.	1	Workflow system connecting mammography room and workstations.
7	Cenova 2D Tower System	1	CAD server, and also used for post-processing.
8	Image Checker CAD (9.4) License for One FFDM.	1	License required for using CAD. This is a one-time fee.
9	Film Digitizing System	1	Digitizes analog films to digital for comparison purposes.
10	Mammography Chair	1	A special chair needed for patients who cannot stand to safely have their mammogram performed.
11	Laser Imager Printer	1	Prints high resolution copies of the mammograms to send to surgeons and oncologists, and to use in the OR.
12	Barcode Scanner	1	Allows selection of individual patient file for interpretation.
13	MRS V7 SQL Reporting System	1	MQSA requires that the facility develop and maintain a database that tracks recall rates from screening, true and false positive and true and false negative rates, sensitivity, specificity, and cancer detection rate. A reporting system is required to build the required database and produce the federally required quality audit. Components below needed for the reporting system. The reporting system is currently valued into the existing mammography room.
14	Worksheet Printing Module	1	Database reports are required for federal tracking purposes. This is used to generate reports for MQSA.
15	Site License	1	License for site to use the reporting system. This is a one-time fee.
16	Additional Concurrent User License	3	Licenses for radiologists to use the reporting system. A minimum of three additional licenses is typical.
17	Densitometer	1	Required for MQSA.

We also received specialty society recommendations for a new Equipment Item, a physician PACS mammography workstation. We note that we discuss physician PACS workstation in section II.A of this rule. The items that comprise the physician PACS mammography workstation are listed in Table 18. We are requesting public comment as to the appropriateness of this list and if some items are indirect expenses or belong in other codes. We also invite commenters to provide any invoices that would help with future pricing of these items.

TABLE 18—PHYSICIAN PACS MAMMOGRAPHY WORKSTATION

PC Tower.
Monitors 5 MP (mammo) (x2).
3rd & 4th monitor (for speech recognition, etc.).
Admin Monitor (the extra working monitor).
Keyboard & Mouse.

TABLE 18—PHYSICIAN PACS MAMMOGRAPHY WORKSTATION—Continued

Powerscribe Microphone.
Software—SV APP SYNC 1.3.0.
Software—R2 Cenova.

We also note that for CY 2015, the CPT Editorial Panel created CPT codes 77061, 77062, and 77063 to describe unilateral, bilateral, and screening digital breast tomosynthesis, respectively. CPT code 77063 is an add-on code to 77057, the CPT code for screening mammography. To be consistent with our use of G codes for digital mammography, we did not implement two of these three CPT codes for Medicare purposes. We only adopted CPT code 77063 an add-on code to G0202. Instead of adopting stand-alone codes 77061 and 77062, we created a new code, G0279 Diagnostic digital breast tomosynthesis, as an add-on code to the diagnostic digital mammography codes G0204 and G0206 and assigned it values based on CPT code 77063. Pending revaluation of the mammography codes using direct PE inputs, we propose to maintain the current coding structure for digital breast tomosynthesis with the technical change that G0279 be reported with 770X1 or 770X2 as the replacement codes for G0204 and G0206.

(31) Microslide Consultation (CPT Codes 88321, 88323, and 88325)

CPT codes 88321, 88323, and 88325 were reviewed by the RUC in April 2014 for their direct PE inputs only, and the CMS refined values were included in the CY 2016 PFS final rule with comment period. The family of codes was reviewed again at the January 2016 RUC meeting for both work values and direct PE inputs, and new recommendations were submitted to CMS as part of the CY 2017 PFS rulemaking cycle.

In the CY 2016 PFS final rule with comment period, we finalized our proposal to remove many of the inputs for clinical labor, supplies, and equipment for CPT code 88325. The descriptor for this code did not state that slide preparation was taking place, and therefore, we refined the labor, supplies, and equipment inputs to align with the inputs recommended for CPT code 88321, which also does not include the preparation of slides. After further discussion with pathologists and consideration of comments received, we have been persuaded that slide preparation does take place in conjunction with the service described by CPT code 88325. In the RUC-recommended direct PE inputs from the January 2016 meeting, the labor, supplies, and equipment inputs related to slide preparation were added once again to CPT code 88325. We are proposing to accept these restorations related to slide preparation without refinement.

Regarding the clinical labor direct PE inputs, we are proposing to assign 1 minute of L037B clinical labor for "Complete workload recording logs. Collate slides and paperwork. Deliver to pathologist" for CPT codes 88323 and 88325. We are maintaining this at the current value for CPT code 88323, and adding this 1 minute to CPT code 88325 based on our new understanding that slide preparation is undertaken as part of the service described by this code. We are proposing to remove the clinical labor for "Assemble and deliver slides with paperwork to pathologists" from all three codes, as we believe this clinical labor is redundant with the labor assigned for "Complete workload recording logs." We are similarly proposing to remove the clinical labor for "Clean equipment while performing service" from CPT codes 88323 and 88325, as we believe it to be redundant with the clinical labor assigned for "Clean room/equipment following procedure."

We are proposing to maintain the quantity of the "stain, hematoxylin" supply (SL135) at 16 ml for CPT codes 88323 and 88325, as opposed to the RUC-recommended quantity of 32 ml. The RUC recommendation stated that the hematoxylin supply does not include eosin and should not be redundant; the stains are not mixed together, but are instead sequential. The recommendation also made a comparison to the use of the hematoxylin supply quantity in CPT code 88305. However, we note that CPT code 88305 does not include 8 ml of eosin stain (SL201), but instead 8 gm of eosin solution (SL063), and these are not the same supply. Therefore we do not agree that a direct comparison of the supply quantities is the most accurate way to value these procedures. For CPT codes 88323 and 88325, we continue to note that the prior supply inputs for these procedures had quantity 2.4 of the eosin solution (SL063) and quantity 4.8 of the hematoxylin stain (SL135); in other words, a 1:2 ratio between the eosin and hematoxylin. We are proposing to maintain that 1:2 ratio with 8 ml of the eosin stain (SL201) and 16 ml of the hematoxylin stain (SL135).

We are also proposing to update the use of the eosin solution (sometimes listed as "eosin y") in our supply database. We believe that the eosin solution supply (SL063), which is measured in grams, reflects an older process of creating eosin stains by hand. This is in contrast to the eosin stain supply (SL201), which is measured in milliliters, and can be ordered in a state that is ready for staining immediately. We do not believe that the use of eosin solution would reflect typical lab practice today, with the readily availability for purchase of inexpensive eosin staining materials. We also note that in the CY 2016 PFS final rule with comment period, we removed 8 gm of the eosin solution and replaced it with 8 ml of the eosin stain, and this substitution was accepted without further change in the most recent set of RUC recommendations. As a result, we are proposing to update the price of the eosin stain supply from $0.044 per ml to $0.068 per ml to reflect the current cost of the supply. We are also proposing to use CPT codes 88323 and 88325 as a model, and replace the use of eosin solution with an equal quantity of eosin stain for the rest of the codes that make use of this supply. This applies to 15 other CPT codes: 88302 (Level II—Surgical pathology, gross and microscopic examination), 88304 (Level III—Surgical pathology, gross and microscopic examination), 88305 (Level IV—Surgical pathology, gross and microscopic examination), 88307 (Level V—Surgical pathology, gross and microscopic examination), 88309 (Level VI—Surgical pathology, gross and microscopic examination), 88364 (In situ hybridization (*e.g.*, FISH), per specimen; each additional single probe stain procedure), 88365 (In situ hybridization (*e.g.*, FISH), per specimen; initial single probe stain procedure), 88366 (In situ hybridization (*e.g.*, FISH), per specimen; each multiplex probe stain procedure), 88367 (Morphometric analysis, in situ hybridization (quantitative or semi-quantitative), using computer-assisted technology, per specimen; initial single probe stain procedure), 88368 (Morphometric analysis, in situ hybridization (quantitative or semi-quantitative), manual, per specimen; initial single probe stain procedure), 88369 (Morphometric analysis, in situ hybridization (quantitative or semi-quantitative), manual, per specimen; each additional single probe stain procedure), 88373 (Morphometric analysis, in situ hybridization (quantitative or semi-quantitative), using computer-assisted technology, per specimen; each additional single probe stain procedure), 88374 (Morphometric analysis, in situ hybridization (quantitative or semi-quantitative), using computer-assisted technology, per specimen; each multiplex probe stain procedure), 88377 (Morphometric analysis, in situ hybridization (quantitative or semi-quantitative), manual, per specimen; each multiplex probe stain procedure), and G0416 (Surgical pathology, gross and microscopic examinations, for prostate needle biopsy, any method).

(32) Closure of Paravalvular Leak (CPT Codes 935X1, 935X2, and 935X3)

The CPT Editorial Committee developed three new codes (two base codes and one add-on code) to describe paravalvular leak closure procedures that were previously reported using an unlisted code. The RUC recommended a work RVU of 17.97 for CPT code 935X2. We are proposing a work RVU of 14.50 for CPT code 935X2, a direct crosswalk from CPT code 37227. We believe that a direct crosswalk to CPT code 37227 accurately reflects the time and intensity described in CPT code 935X2 since CPT code 37227 also describes a transcatheter procedure with similar service times.

To maintain relativity among the codes in this family, we are proposing refinements to the recommended work RVUs for CPT code 935X1. The RUC noted the additional work associated with CPT code 935X1 compared to CPT code 935X2 was due to the addition of a transseptal puncture to access the mitral valve. The RUC identified a work RVU of 3.73 for a transseptal puncture. Therefore, for CPT code 935X1, we are proposing a work RVU of 18.23 arrived at by using our proposed work RVU for CPT code 935X2 (14.50) and adding the value of a transseptal puncture (3.73).

CPT code 935X3 is an add-on code used to report placement of additional occlusion devices for percutaneous transcatheter paravalvular leak closure, performed in conjunction with either an initial mitral or aortic paravalvular leak closure. The RUC recommended a work RVU of 8.00 for this code. We considered applying the relative increment between CPT codes 935X1 and 935X2, however, we believe that a direct crosswalk to CPT code 35572, with a work RVU of 6.81, more accurately reflects the time and intensity of furnishing the service. Therefore, for CPT code 935X3, we are proposing a work RVU of 6.81.

(33) Electroencephalogram (EEG) (CPT Codes 95812, 95813, and 95957)

In February 2016, the RUC submitted recommendations for work and direct PE inputs for CPT codes 95812, 95813, and 95957. We are proposing to use the RUC-recommended physician work and direct PE inputs for CPT code 95957 and to use the RUC-recommended work RVUs for CPT codes 95812 and 95813.

In the CY 2016 PFS final rule with comment period (80 FR 70886), we finalized direct PE input refinements for several clinical labor times for CPT codes 95812 and 95813. The RUC's February 2016 PE summary of recommendations indicated that the specialty society expert panel disagreed with CMS' refinements to clinical labor time for these two codes. The RUC recommended 62 minutes for clinical labor task "perform procedure" for CPT code 95812 and 96 minutes for the same clinical labor task for CPT code 95813, similar to the values recommended by the RUC in April 2014.

We are proposing to maintain the CMS-refined CY 2016 PE inputs for clinical labor task "perform procedure" for CPT codes 95812 (50 minutes) and 95813 (80 minutes). The PE summary of recommendations state that CPT code 95812 requires 50 minutes of clinical labor time for EEG recording, and CPT code 95813 requires 80 minutes of clinical labor time for the same clinical labor task.

(34) Parent, Caregiver-Focused Health Risk Assessment (CPT Code 961X0)

In October 2015, the CPT Editorial Panel created two new PE-only codes, 961X0 (Administration of patient-focused health risk assessment instrument (*e.g.*, health hazard appraisal) with scoring and documentation, per standardized instrument) and 961X1 (Administration of caregiver-focused health risk assessment instrument (*e.g.*, depression inventory) for the benefit of the patient, with scoring and documentation, per standardized instrument). For CPT code 961X0, we are proposing the RUC-recommended direct PE inputs. For CPT code 961X1, the service is furnished to a patient who may not be a Medicare beneficiary and thus we do not believe would be eligible for Medicare payment. We are proposing to assign a procedure status of I (Not valid for Medicare purposes) for CPT code 961X1.

We note that we believe that this code describes a service that is frequently reasonable and necessary in the treatment of illness or injury, such as when there has been a change in health status. However, when the service described by CPT code 961X0 is explicitly included in another service being furnished, such as the Annual Wellness Visit (AWV), this code should not be billed separately, much like other codes that describe services included in codes with broader descriptions. We also note that this service should not be billed separately if furnished as a preventive service as it would describe a non-covered service. However, we are also seeking comment on whether this service may be better categorized as an add-on code and welcome stakeholder input regarding whether or not there are circumstances when this service might be furnished as a stand-alone service.

(35) Reflectance Confocal Microscopy (CPT Codes 96931, 96932, 96933, 96934, 96935, and 96936)

For CY 2015, the CPT Editorial panel established six new Category I codes to describe reflectance confocal microscopy (RCM) for imaging of skin. For CPT codes 96931 and 96933, the specialty society and the RUC agreed that the physician work required for both codes were identical, and therefore, should be valued the same. The RUC recommended a work RVU of 0.80 for CPT codes 96931 and 96933 based on the 25th percentile of the survey. Based on the similarity of the services being performed in CPT codes 96931 and 96933 and the identical intra-service times of 96931, 96933 and 88305, the key reference code from the survey, we believe a direct crosswalk from CPT code 88305 to 96931 and 96933 would more accurately reflect the work involved in furnishing the procedure. Therefore, for CY 2017 we are proposing a value of 0.75 RVUs for CPT codes 96931 and 96933. In addition, we are removing 3 minutes of preservice time in CPT codes 96931 and 96933 since it is not included in CPT code 88305 and as a result, we do not believe it is appropriate in CPT codes 96931 and 96933 either.

For CPT codes 96934 and 96936 the specialty society and the RUC agreed that the physician work required for both codes were identical, and therefore, should be valued the same. In its recommendation, the RUC stated that it believed the survey respondents somewhat overestimated the work for CPT code 96934 with the 25th percentile yielding a work RVU of 0.79. Consequently, the RUC reviewed the survey results from CPT code 96936 and agreed that the 25th percentile work RVU of 0.76 accurately accounted for the work involved for the service. Therefore, the RUC recommended a work RVU of 0.76 for CPT codes 96934 and 96936.

We believe that the incremental difference between the RUC-recommended values for the base and add-on codes accurately captures the difference in work between the code pairs. However, because we valued the base codes differently than the RUC, we are proposing values for the add-on codes that maintain the RUC's 0.04 increment instead of the RUC-recommended values. Therefore we are proposing a work RVU of 0.71 for CPT codes 96934 and 96936.

We are also proposing to reduce the preservice clinical labor for Patient clinical information and questionnaire reviewed by technologist, order from physician confirmed and exam protocoled by physician CPT codes 96934 and 93936 as this work is performed in the two CPT base codes 93931 and 93933. The service period clinical labor for "Prepare and position patient/monitor patient/set up IV" was reduced from 2 to 1 minute for CPT codes 93934 and 93936 since we believe that less positioning time is needed with subsequent lesions. The service period clinical labor for "Other Clinical Activity—Review imaging with interpreting physician" was refined to zero minutes for CPT codes 96933 and 96936 as these are interpretation and report only codes and not image acquisition.

(36) Evaluative Procedures for Physical Therapy and Occupational Therapy (CPT Codes 97X61, 97X62, 97X63, 97X64, 97X65, 97X66, 97X67, 97X68)

For CY 2017, the CPT Editorial Panel deleted four CPT codes (97001, 97002, 97003, and 97004) and created eight new CPT codes (97X61–97X68) to describe the evaluative procedures furnished by physical therapists and occupational therapists. There are three new codes, stratified by complexity, to replace a single code, 97001, for physical therapy (PT) evaluation, three new codes, also stratified by complexity, to replace a single code, 97003, for occupational therapy (OT) evaluation, and one new code each to replace the reevaluation codes for physical and occupational therapy—97002 and 97004. Table 19 includes the long descriptors and the required components of each of the eight new CPT codes for the PT and OT services.

The CPT Editorial Panel's creation of the new codes for PT and OT evaluative procedures grew out of a CPT workgroup that was originally convened in January 2012 when contemplating major revision of the Physical Medicine and Rehabilitation CPT section of codes in response to our nomination of therapy codes as potentially misvalued codes, including CPT code 97001 (and, as a result, all four codes in the family) in the CY 2012 PFS proposed rule.

In reviewing the eight new CPT codes for evaluative procedures, the HCPAC forwarded recommendations for work RVUs and direct PE inputs for each code. Currently, CPT codes 97001 and 97003 both have a work RVU of 1.20, and CPT codes 97002 and 97004 both have a work RVU of 0.60. These CPT codes have reflected the same work RVUs since CY 1998 when we accepted the HCPAC values during CY 1998 rulemaking.

i. Valuation of Evaluation Codes

The HCPAC submitted work RVU recommendations for each of the six new PT and OT evaluation codes. These recommendations are intended to be work neutral relative to the valuation for the previous single evaluation code for PT and OT, respectively. However, that assessment for each family of codes is dependent on the accuracy of the utilization forecast for the different complexity levels within the PT or OT family. As used in this section, work neutrality is distinct from the budget neutrality that is applied broadly in the PFS. Specifically, work neutrality is intended to reflect that despite changes in coding, the overall amount of work RVUs for a set of services is held constant from one year to the next. For example, if a service is reported using a single code with a work RVU of 2.0 for one year but that same service would be reported using two codes, one for "simple" and another for "complex" in the subsequent year valued at 1.0 and 3.0 respectively, work neutrality could only be attained if exactly half the services were reported using each of the two new codes. If more than half of the services were reported using the "simple" code, then there would be fewer overall work RVUs. If more than half of the services were reported using the "complex" code, then there would be more overall work RVUs. Therefore, work neutrality can only be assessed with an understanding of the relative frequency of how often particular codes will be reported.

The HCPAC recommended a work RVU of 0.75 for CPT code 97X61, a work RVU of 1.18 for CPT code 97X62, and a work RVU of 1.5 for CPT code 97X63. The PT specialty society projected that the moderate complexity evaluation code would be reported 50 percent of the time because it is the typical evaluation, and the CPT codes for the low and high complexity evaluations are each expected to be billed 25 percent of the time. The HCPAC-recommended work RVU of 1.18 for CPT code 97X62 represents the survey median with 30 minutes of intraservice time, 10 minutes of preservice time, and 15 minutes postservice time. The HCPAC notes this work value is appropriately ranked between levels 2 and 3 of the E/M office visit codes for new patients.

The HCPAC recommended a work RVU of 0.88 for CPT code 97X65, a work RVU of 1.20 for CPT code 97X66, and a work RVU of 1.70 for CPT code 97X67. For the OT codes, work neutrality would be achieved only with a projected utilization in which the low-complexity evaluation is billed 50 percent of the time; the moderate-complexity evaluation is billed 40 percent of the time, and the high-complexity evaluation only billed 10 percent of the time. For purposes of calculating work neutrality, the HCPAC recommended assuming that the low-complexity code will be most frequently reported even though the HCPAC-recommended work RVU of 1.20 and 45 minutes of intraservice time for moderate complexity code is identical to that of the current OT evaluation code. The HCPAC believes that the work RVU of 1.20 is appropriately ranked between 99202 and 99203, levels 2 and 3 for E/M office visits for new outpatients.

ii. Valuation of Evaluation Codes and Discussion of PAMA

In our review of the HCPAC recommendations, we noted the work neutrality and the inherent reliance on the utilization assumptions. We considered the three complexity levels for the PT evaluations and the three complexity levels for the OT evaluations; and we also considered the evaluation services described by the codes as a whole. The varying work RVUs and the dependence on utilization for each complexity level to ensure work neutrality in the PT and OT code families make it difficult for us evaluate the HCPAC's recommended values or to predict with a high degree of certainty whether physical and occupational therapists will actually bill for these services at the same rate forecast by their respective specialty societies.

We are concerned that the coding stratification in the PT and OT evaluation codes may result in upcoding incentives, especially while physical and occupational therapists gain familiarity and expertise in the differential coding of the new PT and OT evaluation codes that now include the typical face-to-face times and new required components that are not enumerated in the current codes. We are also concerned that stratified payment rates may provide, in some cases, a payment incentive to therapists to upcode to a higher complexity level than was actually furnished to receive a higher payment.

We understand that there may be multiple reasons for the CPT Editorial Panel to stratify coding for OT and PT evaluation codes based on complexity. We also note that the codes will be used by payers in addition to Medicare, and other payers may have direct interest in making such differential payment based on complexity of OT and PT evaluation. Given our concerns regarding appropriate valuation, work neutrality, and potential upcoding, however, we do not believe that making different payment based on the reported complexity for these services is, at current, advantageous for Medicare or Medicare beneficiaries.

Given the advantages inherent and public interest in using CPT codes once they become part of the code set, we are proposing to adopt the new CPT codes for use in Medicare for CY 2017. However, given our concerns about appropriate pricing and payment for the stratified services, we are proposing to price the services described by these stratified codes as a group instead of individually. To do that, we are proposing to utilize the authority in section 220(f) of the Protecting Access to Medicare Act (PAMA), which revised section 1848(c)(2)(C) of the Act to authorize the Secretary to determine RVUs for groups of services, rather than determining RVUs at the individual service level. We believe that using this authority instead of proposing to make payment based on Medicare G-codes will preserve consistency in the code set across payers, thus lessening burden on providers, while retaining flexibilities that are beneficial to Medicare.

We propose a work RVU of 1.20 for both the PT and the OT evaluation groups of services. We are proposing this work RVU because we believe it best represents the typical PT and OT evaluation. This is the value recommended by the HCPAC for the OT moderate-complexity evaluation and nearly the same work RVU for corresponding PT evaluation (1.18). Additionally, 1.20 work RVUs is the long-standing value for the current evaluation codes, 97001 and 97003, and, thus, assures work neutrality without reliance on particular assumptions about utilization, which we believe was the intent of the HCPAC recommendation.

Because we are proposing to use the same work RVU for the six evaluation codes, we are not addressing any additional concerns about the utilization assumptions recommended to us. By proposing the same work values for each code in the family, there will be no ratesetting impact to work neutrality. As such, we are not revising the utilization crosswalks as projected by the respective therapy specialties to achieve work neutrality. However, were we to value each code in the PT or OT evaluation families individually, we would seek objective data from stakeholders to support the utilization crosswalks, particularly those for the OT family in which the low-level complexity evaluation is depicted as typical and the high-complexity is projected to be billed infrequently at 10 percent of the overall number of OT evaluations.

We are proposing to use the direct PE inputs forwarded by the HCPAC (with the refinements described below) for the typical PT evaluation and also for the typical OT evaluation in the development of PE RVUs for the PT and OT codes as a group of services. For the PT codes, we are proposing to use the recommended inputs for the moderate-complexity code for the direct PE inputs of all three codes based on its assumption as the typical service. Our proposed direct PE inputs reflect the recommended values minus 2 minutes of physical therapist assistant (PTA) time in the service period because we believe that PTA tasks to administer certain assessment tools are appropriately included as part of the physical therapist's work and the time of the PTA to explain and/or score self-reported outcome measures is not separately included in the clinical labor of other codes. We are proposing to include the recommended four sheets of laser paper without an association to a specific equipment item, but we are seeking comment regarding the paper's use.

For the OT evaluation codes, we considered proposing to use the direct PE inputs for the low-complexity evaluation because the OT specialty organization believes it represents the typical OT evaluation service with a projected 50 percent utilization rate. However, we propose to use the moderate-level direct inputs instead, because the direct PE for this level is based on a vignette that is valued with the same intraservice time, 45 minutes, as the current code, CPT code 97003. Consequently, we propose to use the recommended direct PE inputs for the moderate-complexity code for use in developing PE RVUs for this group of services.

Our proposed direct PE inputs reflect the recommended values minus 2 minutes of occupational therapist assistant (OTA) time in the service period because we believe that OTA tasks to administer certain assessment tools are appropriately included as part of the occupational therapist's work and the time of the OTA to explain and/or score self-reported outcome measures is not separately included in the clinical labor of other codes. We also rounded up the recommended 6.8 minutes to 7 minutes to represent the time the OTA assists the occupational therapist during the intraservice time period. For the Vision Kit equipment item, our proposed price reflects the submitted invoice that clearly defined a kit.

iii. Valuation of Reevaluation Codes

The recommendations the HCPAC sent to us for the PT and OT reevaluation codes are not work neutral. For the new PT reevaluation code, CPT code 97X64, the HCPAC recommended a work RVU of 0.75 compared to the work RVU of 0.60 for CPT code 97002. This recommended work RVU falls between the 25th percentile of the survey and the survey's median value and was based on a direct crosswalk to CPT code 95992 for canalith repositioning with 20 minutes intraservice time and 10 minutes immediate postservice time. The HCPAC supported this 0.15 work RVU increase based on an anomalous relationship between PT services and E/M office visit codes for established patients, noting that physician E/M codes have historically been used as a relative comparison. The HCPAC stated its 0.75 work RVU recommendation for code 97X64 appropriately ranks it between the key reference codes for this service 99212 and 99213, levels 2 and 3 E/M office-visit codes for established patients.

The HCPAC provided a work RVU of 0.80 for the OT reevaluation code, CPT code 97X68, based on the 25th percentile of the survey, which represents an increase over the current work RVU of 0.60 for CPT code 97004. This work value includes 30 minutes of intraservice time, 5 minutes preservice time, and 10 minutes immediate postservice time. The HCPAC noted that the increase in work compared to the PT reevaluation code (0.75) is because the occupational therapist spends more time observing and assessing the patient and, in general, the OT patient typically has more functional and cognitive disabilities. The HCPAC recommendation notes that the 0.80 work RVU recommendation appropriately ranks it between the level 1 and 2 E/M office-visit codes for new patients.

The HCPAC's recommended increases to work RVUs for the PT and OT reevaluation codes are not work neutral. We are unclear why the HCPAC did not maintain work neutrality for the OT and PT reevaluation codes since maintaining work neutrality was important to the establishment of the six new evaluation codes. We are proposing to maintain the overall work RVUs for these services by proposing 0.60 work RVUs for CPT codes 97X64 and 97X68, consistent with the work RVUs for the deleted reevaluation codes. We are seeking comments from stakeholders on whether there are reasons that the reevaluation codes should be revalued without regard to work neutrality particularly given the HCPAC's interest in preserving work neutrality for the new evaluation codes.

We are proposing the HCPAC-recommended direct PE inputs for CPT code 97X64 with a reduction in time for the PTA by 1 minute (from 5 to 4) in the service period– the line for "Other Clinical Activity"—because the time to explain and score the self-reported outcome measure (for example, Oswestry) is not separately included in the clinical labor of other codes.

We are proposing the HCPAC-recommended direct PE inputs for CPT code 97X68 with a reduction in time for the OTA by 1 minute (from 3 to 2) in the service period—the line for "Other Clinical Activity"—for the same reason we reduced the corresponding line for PTAs—because the time to explain and score any patient-self-administered functional and/or other standardized outcome measure is not separately included in the clinical labor of other codes.

Because the new CPT code descriptors contain new coding requirements for each complexity level, we seek comment from the PT and OT specialty organizations as well as other stakeholders to clarify how therapists will be educated to distinguish the required complexity level components and the selection of the number of elements that impact the plan of care. For example, for the OT codes, we invite comment on how to define performance deficits, what process the occupational therapist uses to identify the number of these performance deficits that result in activity limitations, and performance factors needed for each complexity level. For the PT codes, we would like more information about how the physical therapist differentiates the number of personal factors that actually affect the plan of care. We would also be interested in understanding more about how the physical therapist selects the number of elements from any of the body structures and functions, activity limitations, and/or participation restrictions to make sure there is no duplication during the physical therapist's examination of body systems.

iv. Always Therapy Codes

It is also important to note that CMS defines the codes for these evaluative services as "always therapy." This means that they always represent therapy services regardless of who performs them and always require a therapy modifier, GP or GO, to signify that the services are furnished under a PT or OT plan of care, respectively. These codes will also be subject to the therapy MPPR and to statutory therapy caps.

TABLE 19—CPT LONG DESCRIPTORS FOR PHYSICAL MEDICINE AND REHABILITATION

New CPT code	CPT long descriptors for physical medicine and rehabilitation
97X61	Physical therapy evaluation: Low complexity, requiring these components: • A history with no personal factors and/or comorbidities that impact the plan of care; • An examination of body system(s) using standardized tests and measures addressing 1–2 elements from any of the following: Body structures and functions, activity limitations, and/or participation restrictions; • A clinical presentation with stable and/or uncomplicated characteristics; and • Clinical decision making of low complexity using standardized patient assessment instrument and/or measurable assessment of functional outcome. Typically, 20 minutes are spent face-to-face with the patient and/or family.
97X62	Physical therapy evaluation: Moderate complexity, requiring these components: • A history of present problem with 1–2 personal factors and/or comorbidities that impact the plan of care; • An examination of body systems using standardized tests and measures in addressing a total of 3 or more elements from any of the following: Body structures and functions, activity limitations, and/or participation restrictions; • An evolving clinical presentation with changing characteristics; and • Clinical decision making of moderate complexity using standardized patient assessment instrument and/or measurable assessment of functional outcome. Typically, 30 minutes are spent face-to-face with the patient and/or family.
97X63	Physical therapy evaluation: High complexity, requiring these components: • A history of present problem with 3 or more personal factors and/or comorbidities that impact the plan of care; • An examination of body systems using standardized tests and measures addressing a total of 4 or more elements from any of the following: Body structures and functions, activity limitations, and/or participation restrictions; • A clinical presentation with unstable and unpredictable characteristics; and • Clinical decision making of high complexity using standardized patient assessment instrument and/or measurable assessment of functional outcome. Typically, 45 minutes are spent face-to-face with the patient and/or family.
97X64	Reevaluation of physical therapy established plan of care, requiring these components: • An examination including a review of history and use of standardized tests and measures is required; and • Revised plan of care using a standardized patient assessment instrument and/or measurable assessment of functional outcome Typically, 20 minutes are spent face-to-face with the patient and/or family.
97X65	Occupational therapy evaluation, low complexity, requiring these components: • An occupational profile and medical and therapy history, which includes a brief history including review of medical and/or therapy records relating to the presenting problem; • An assessment(s) that identifies 1–3 performance deficits (*i.e.*, relating to physical, cognitive, or psychosocial skills) that result in activity limitations and/or participation restrictions; and • Clinical decision making of low complexity, which includes an analysis of the occupational profile, analysis of data from problem-focused assessment(s), and consideration of a limited number of treatment options. Patient presents with no comorbidities that affect occupational performance. Modification of tasks or assistance (*e.g.*, physical or verbal) with assessment(s) is not necessary to enable completion of evaluation component. Typically, 30 minutes are spent face-to-face with the patient and/or family.

TABLE 19—CPT LONG DESCRIPTORS FOR PHYSICAL MEDICINE AND REHABILITATION—Continued

New CPT code	CPT long descriptors for physical medicine and rehabilitation
97X66	Occupational therapy evaluation, moderate complexity, requiring these components: • An occupational profile and medical and therapy history, which includes an expanded review of medical and/or therapy records and additional review of physical, cognitive, or psychosocial history related to current functional performance; • An assessment(s) that identifies 3–5 performance deficits (*i.e.*, relating to physical, cognitive, or psychosocial skills) that result in activity limitations and/or participation restrictions; and • Clinical decision making of moderate analytic complexity, which includes an analysis of the occupational profile, analysis of data from detailed assessment(s), and consideration of several treatment options. Patient may present with comorbidities that affect occupational performance. Minimal to moderate modification of tasks or assistance (*e.g.*, physical or verbal) with assessment(s) is necessary to enable patient to complete evaluation component. Typically, 45 minutes are spent face-to-face with the patient and/or family.
97X67	Occupational therapy evaluation, high complexity, requiring these components: • An occupational profile and medical and therapy history, which includes review of medical and/or therapy records and extensive additional review of physical, cognitive, or psychosocial history related to current functional performance; • An assessment(s) that identify 5 or more performance deficits (*i.e.*, relating to physical, cognitive, or psychosocial skills) that result in activity limitations and/or participation restrictions; and • A clinical decision-making is of high analytic complexity, which includes an analysis of the patient profile, analysis of data from comprehensive assessment(s), and consideration of multiple treatment options. Patient presents with comorbidities that affect occupational performance. Significant modification of tasks or assistance (*e.g.*, physical or verbal) with assessment(s) is necessary to enable patient to complete evaluation component. Typically, 60 minutes are spent face-to-face with the patient and/or family.
97X68	Reevaluation of occupational therapy established plan of care, requiring these components: • An assessment of changes in patient functional or medical status with revised plan of care; • An update to the initial occupational profile to reflect changes in condition or environment that affect future interventions and/or goals; and • A revised plan of care. A formal reevaluation is performed when there is a documented change in functional status or a significant change to the plan of care is required. Typically, 30 minutes are spent face-to-face with the patient and/or family.

v. Potentially Misvalued Therapy Codes

Since 2010, in addition to the codes for evaluative services, CMS has periodically added codes that represent therapy services to the list of potentially misvalued codes. The current list of 10 therapy codes was based on the statutory category "codes that account for the majority of spending under the physician fee schedule," as specified in section 1848(c)(2)(K)(ii)(VII) of the Act. We understand that the therapy specialty organizations have pursued the development of coding changes through the CPT process for these modality and procedures services. While we understand that, in some cases, it may take several years to develop appropriate coding revisions, we are, in the meantime, seeking information regarding appropriate valuation for the existing codes. See Table 20.

TABLE 20—POTENTIALLY MISVALUED CODES IDENTIFIED THROUGH HIGH EXPENDITURE BY SPECIALTY SCREEN

HCPCS code	Short descriptor
97032	Electrical stimulation.
97035	Ultrasound therapy.
97110	Therapeutic exercises.
97112	Neuromuscular reeducation.
97113	Aquatic therapy/exercises.
97116	Gait training therapy.
97140	Manual therapy 1/regions.
97530	Therapeutic activities.
97535	Self care mngment training.
G0283	Elec stim other than wound.

(37) Proposed Valuation of Services Where Moderate Sedation Is an Inherent Part of the Procedure and Proposed Valuation of Moderate Sedation Services (CPT Codes 991X1, 991X2, 991X3, 991X4, 991X5, and 991X6; and HCPCS Code GMMM1)

In the CY 2015 PFS proposed rule (79 FR 40349), we noted that it appeared that practice patterns for endoscopic procedures were changing. Anesthesia services are increasingly being separately reported for endoscopic procedures, meaning that resource costs associated with sedation were no longer incurred by the practitioner reporting the procedure. Subsequently, in the CY 2016 PFS proposed rule (80 FR 41707), we sought public comment and recommendations on approaches to address the appropriate valuation of moderate sedation related to the approximately 400 diagnostic and therapeutic procedures for which the CPT Editorial Committee has determined that moderate sedation is an inherent part of furnishing the service. The CPT Editorial Committee created separate codes for reporting of moderate sedation services.

TABLE 21—MODERATE SEDATION CODES AND DESCRIPTORS

CPT/HCPCS code	Descriptor
991X1	Moderate sedation services provided by the same physician or other qualified health care professional performing the diagnostic or therapeutic service that the sedation supports, requiring the presence of an independent trained observer to assist in the monitoring of the patient's level of consciousness and physiological status; initial 15 minutes of intra-service time, patient younger than 5 years of age.

TABLE 21—MODERATE SEDATION CODES AND DESCRIPTORS—Continued

CPT/HCPCS code	Descriptor
991X2	Moderate sedation services provided by the same physician or other qualified health care professional performing the diagnostic or therapeutic service that the sedation supports, requiring the presence of an independent trained observer to assist in the monitoring of the patient's level of consciousness and physiological status; initial 15 minutes of intra-service time, patient age 5 years or older.
991X3	Moderate sedation services provided by a physician or other qualified health care professional other than the physician or other qualified health care professional performing the diagnostic or therapeutic service that the sedation supports; initial 15 minutes of intra-service time, patient younger than 5 years of age.
991X4	Moderate sedation services provided by a physician or other qualified health care professional other than the physician or other qualified health care professional performing the diagnostic or therapeutic service that the sedation supports; initial 15 minutes of intra-service time, patient age 5 years or older.
991X5	Moderate sedation services provided by the same physician or other qualified health care professional performing the diagnostic or therapeutic service that the sedation supports, requiring the presence of an independent trained observer to assist in the monitoring of the patient's level of consciousness and physiological status; each additional 15 minutes of intra-service time (List separately in addition to code for primary service).
991X6	Moderate sedation services provided by a physician or other qualified health care professional other than the physician or other qualified health care professional performing the diagnostic or therapeutic service that the sedation supports; each additional 15 minutes intra-service time (List separately in addition to code for primary service).

For the newly created moderate sedation CPT codes, we are proposing to use the RUC-recommended work RVUs for CPT codes 991X1, 991X2, 991X3, and 991X6. CPT codes 991X1 and 991X2 make a distinction between moderate sedation services furnished to patients younger than 5 years of age and patients 5 years or older, with CPT codes 991X3 and 991X4 making a similar distinction. The RUC recommendations include a work RVU increment of 0.25 between CPT code 991X1 and 991X2. For CPT code 991X4, we are proposing a work RVU of 1.65 to maintain the 0.25 increment relative to CPT code 991X3 (a RUC-recommended work RVU of 1.90) and maintain relativity among the CPT codes in this family. We are proposing to use the RUC-recommended direct PE inputs for all six codes.

When moderate sedation is reported for Medicare beneficiaries, we expect that it would most frequently reported using the code that describes moderate sedation furnished by the same person who also performs the primary procedure for patients 5 years of age or older. Under the new coding structure, these services would be reported using CPT code 991X2. Stakeholders have presented information that illustrates that the specialty group survey data regarding the work involved in furnishing the moderate sedation described by CPT code 991X2 showed a significant bimodal distribution between procedural services furnished by gastroenterologists (GI) and those services furnished by other specialties. The GI societies' survey data reported a median valuation of 0.10 work RVUs for moderate sedation furnished by the same person furnishing the base procedure; all other specialty groups (combined) reported a median valuation of 0.25 work RVUs. Given the significant volume of moderate sedation furnished by GI practitioners and the significant difference in RVUs reported in the survey data, we are proposing to make payment using a gastrointestinal (GI) endoscopy-specific moderate sedation code GMMM1 that would be used in lieu of the new CPT moderate sedation coding used more broadly: GMMM1: Moderate sedation services provided by the same physician or other qualified health care professional performing a gastrointestinal endoscopic service (excluding biliary procedures) that sedation supports, requiring the presence of an independent trained observer to assist in the monitoring of the patient's level of consciousness and physiological status; initial 15 minutes of intra-service time; patient age 5 years or older.

We are proposing to value GMMM1 at 0.10 work RVUs based on the median survey result for GI respondents in the survey data. We are proposing that when moderate sedation services are furnished by the same practitioner reporting the GI endoscopy procedure, practitioners would report the sedation services using GMMM1 instead of 991X2. In all other cases, we propose that practitioners would report moderate sedation using one of the new moderate sedation CPT codes consistent with CPT guidance. This would include the full range of codes for those furnishing moderate sedation with the remaining (non-GI endoscopy) base procedures as well as for the other circumstances during which moderate sedation is furnished along with a GI endoscopy (for example, to a patient under 5 years of age or for a biliary procedure, the endoscopist furnishing moderate sedation should not use GMMM1, but instead use the appropriate CPT code; see Table 22 for more information about when GMMM1 should be used in lieu of the newly created moderate sedation CPT codes).

In addition to providing recommended values for the new codes used to separately report moderate sedation, the RUC has provided recommendations that value the procedural services without moderate sedation. However, the RUC recommends removing fewer RVUs from the procedures than it recommends for valuing the sedation services. In other words, the RUC is recommending that overall payments for these procedures should be increased now that practitioners will be required to report the sedation services that were previously included as inherent parts of the procedures. We believe that if we were to use the RUC recommendations for re-valuation of the procedural services without refinement, the RVUs currently attributable to the redundant payment for sedation services when anesthesia is separately reported would be used exclusively to increase overall payment for these services. We refer readers to Section II.D.5. of this proposed rule, which includes a more extensive discussion of our general principle that overall resource costs for the procedures including moderate sedation do not inherently change based solely on changes in coding.

To account for the separate billing of moderate sedation services, we are proposing to maintain current values for the procedure codes less the work RVUs associated with the most frequently reported corresponding moderate sedation code so that practitioners furnishing the moderate sedation services previously considered to be inherent in the procedure will have no change in overall work RVUs. Since we are proposing 0.10 work RVUs for moderate sedation for the GI endoscopy procedures, this means we are proposing a corresponding .10 reduction in work RVUs for these procedures. For all other Appendix G procedures that currently include moderate sedation as an inherent part of the procedure, we are proposing to remove 0.25 work RVUs from the current values.

Table 22 lists the existing work RVUs for each applicable service and our proposed refined work RVU using the proposed revaluation methodology described above. Additionally, the table identifies the GI endoscopic services for which we are proposing that GMMM1 would be used to report moderate sedation services. This information will be made available and maintained in the "downloads" section of the PFS Web site at *http://www.cms.gov/Medicare/Medicare-Feefor-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.*

TABLE 22—PROPOSED VALUATIONS FOR ENDOSCOPY SERVICES MINUS MODERATE SEDATION

HCPCS	CY 2016 work RVU	CY 2017 proposed work RVU	Use GMMM1 to report moderate sedation (Y/N)
10030	3.00	2.75	N
19298	6.00	5.75	N
20982	7.27	7.02	N
20983	7.13	6.88	N
22510	8.15	7.90	N
22511	7.58	7.33	N
22512	4.00	4.00	N
22513	8.90	8.65	N
22514	8.24	7.99	N
22515	4.00	4.00	N
22526	6.10	5.85	N
22527	3.03	3.03	N
31615	2.09	1.84	N
31622	2.78	2.53	N
31623	2.88	2.63	N
31624	2.88	2.63	N
31625	3.36	3.11	N
31626	4.16	3.91	N
31627	2.00	2.00	N
31628	3.80	3.55	N
31629	4.00	3.75	N
31632	1.03	1.03	N
31633	1.32	1.32	N
31634	4.00	3.75	N
31635	3.67	3.42	N
31645	3.16	2.91	N
31646	2.72	2.47	N
31647	4.40	4.15	N
31648	4.20	3.95	N
31649	1.44	1.44	N
31651	1.58	1.58	N
31652	4.71	4.46	N
31653	5.21	4.96	N
31654	1.40	1.40	N
31660	4.25	4.00	N
31661	4.50	4.25	N
31725	1.96	1.71	N
32405	1.93	1.68	N
32550	4.17	3.92	N
32551	3.29	3.04	N
32553	3.80	3.55	N
33010	2.24	1.99	N
33011	2.24	1.99	N
33206	7.39	7.14	N
33207	8.05	7.80	N
33208	8.77	8.52	N
33210	3.30	3.05	N
33211	3.39	3.14	N
33212	5.26	5.01	N
33213	5.53	5.28	N
33214	7.84	7.59	N
33216	5.87	5.62	N
33217	5.84	5.59	N
33218	6.07	5.82	N
33220	6.15	5.90	N
33221	5.80	5.55	N
33222	5.10	4.85	N
33223	6.55	6.30	N
33227	5.50	5.25	N
33228	5.77	5.52	N
33229	6.04	5.79	N
33230	6.32	6.07	N
33231	6.59	6.34	N
33233	3.39	3.14	N
33234	7.91	7.66	N
33235	10.15	9.90	N
33240	6.05	5.80	N
33241	3.29	3.04	N
33244	13.99	13.74	N
33249	15.17	14.92	N
33262	6.06	5.81	N
33263	6.33	6.08	N
33264	6.60	6.35	N
33282	3.50	3.25	N
33284	3.00	2.75	N
33990	8.15	7.90	N
33991	11.88	11.63	N
33992	4.00	3.75	N
33993	3.51	3.26	N
35471	10.05	9.80	N
35472	6.90	6.65	N
35475	6.60	6.35	N
35476	5.10	4.85	N
36010	2.43	2.18	N
36140	2.01	1.76	N
36147	3.72	3.47	N
36148	1.00	1.00	N
36200	3.02	2.77	N
36221	4.17	3.92	N
36222	5.53	5.28	N
36223	6.00	5.75	N
36224	6.50	6.25	N
36225	6.00	5.75	N
36226	6.50	6.25	N
36227	2.09	2.09	N
36228	4.25	4.25	N
36245	4.90	4.65	N
36246	5.27	5.02	N
36247	6.29	6.04	N
36248	1.01	1.01	N
36251	5.35	5.10	N
36252	6.99	6.74	N
36253	7.55	7.30	N
36254	8.15	7.90	N
36481	6.98	6.73	N
36555	2.68	2.43	N
36557	5.14	4.89	N
36558	4.84	4.59	N
36560	6.29	6.04	N
36561	6.04	5.79	N
36563	6.24	5.99	N
36565	6.04	5.79	N
36566	6.54	6.29	N
36568	1.92	1.67	N
36570	5.36	5.11	N
36571	5.34	5.09	N
36576	3.24	2.99	N
36578	3.54	3.29	N
36581	3.48	3.23	N
36582	5.24	4.99	N
36583	5.29	5.04	N
36585	4.84	4.59	N
36590	3.35	3.10	N
36870	5.20	4.95	N
37183	7.99	7.74	N
37184	8.66	8.41	N
37185	3.28	3.28	N
37186	4.92	4.92	N
37187	8.03	7.78	N
37188	5.71	5.46	N
37191	4.71	4.46	N
37192	7.35	7.10	N
37193	7.35	7.10	N
37197	6.29	6.04	N
37211	8.00	7.75	N
37212	7.06	6.81	N
37213	5.00	4.75	N
37214	2.74	2.49	N
37215	18.00	17.75	N
37216	0.00	0.00	N
37218	15.00	14.75	N
37220	8.15	7.90	N
37221	10.00	9.75	N
37222	3.73	3.73	N
37223	4.25	4.25	N
37224	9.00	8.75	N
37225	12.00	11.75	N
37226	10.49	10.24	N
37227	14.50	14.25	N
37228	11.00	10.75	N
37229	14.05	13.80	N
37230	13.80	13.55	N
37231	15.00	14.75	N
37232	4.00	4.00	N
37233	6.50	6.50	N
37234	5.50	5.50	N
37235	7.80	7.80	N
37236	9.00	8.75	N
37237	4.25	4.25	N
37238	6.29	6.04	N
37239	2.97	2.97	N
37241	9.00	8.75	N
37242	10.05	9.80	N

TABLE 22—PROPOSED VALUATIONS FOR ENDOSCOPY SERVICES MINUS MODERATE SEDATION—Continued

HCPCS	CY 2016 work RVU	CY 2017 proposed work RVU	Use GMMM1 to report moderate sedation (Y/N)
37243	11.99	11.74	N
37244	14.00	13.75	N
37252	1.80	1.80	N
37253	1.44	1.44	N
43200	1.52	1.42	Y
43201	1.82	1.72	Y
43202	1.82	1.72	Y
43204	2.43	2.33	Y
43205	2.54	2.44	Y
43206	2.39	2.29	Y
43211	4.30	4.20	Y
43212	3.50	3.40	Y
43213	4.73	4.63	Y
43214	3.50	3.40	Y
43215	2.54	2.44	Y
43216	2.40	2.30	Y
43217	2.90	2.80	Y
43220	2.10	2.00	Y
43226	2.34	2.24	Y
43227	2.99	2.89	Y
43229	3.59	3.49	Y
43231	2.90	2.80	Y
43232	3.69	3.59	Y
43233	4.17	4.07	Y
43235	2.19	2.09	Y
43236	2.49	2.39	Y
43237	3.57	3.47	Y
43238	4.26	4.16	Y
43239	2.49	2.39	Y
43240	7.25	7.15	Y
43241	2.59	2.49	Y
43242	4.83	4.73	Y
43243	4.37	4.27	Y
43244	4.50	4.40	Y
43245	3.18	3.08	Y
43246	3.66	3.56	Y
43247	3.21	3.11	Y
43248	3.01	2.91	Y
43249	2.77	2.67	Y
43250	3.07	2.97	Y
43251	3.57	3.47	Y
43252	3.06	2.96	Y
43253	4.83	4.73	Y
43254	4.97	4.87	Y
43255	3.66	3.56	Y
43257	4.25	4.15	Y
43259	4.14	4.04	Y
43260	5.95	5.70	N
43261	6.25	6.00	N
43262	6.60	6.35	N
43263	6.60	6.35	N
43264	6.73	6.48	N
43265	8.03	7.78	N
43266	4.17	3.92	N
43270	4.26	4.01	N
43273	2.24	2.24	N
43274	8.58	8.33	N
43275	6.96	6.71	N
43276	8.94	8.69	N
43277	7.00	6.75	N
43278	8.02	7.77	N
43450	1.38	1.13	N
43453	1.51	1.26	N
44360	2.59	2.49	Y
44361	2.87	2.77	Y
44363	3.49	3.39	Y
44364	3.73	3.63	Y
44365	3.31	3.21	Y
44366	4.40	4.30	Y
44369	4.51	4.41	Y
44370	4.79	4.69	Y
44372	4.40	4.30	Y
44373	3.49	3.39	Y
44376	5.25	5.15	Y
44377	5.52	5.42	Y
44378	7.12	7.02	Y
44379	7.46	7.36	Y
44380	0.97	0.87	Y
44381	1.48	1.38	Y
44382	1.27	1.17	Y
44384	2.95	2.85	Y
44385	1.30	1.20	Y
44386	1.60	1.50	Y
44388	2.82	2.72	Y
44388–53	1.41	1.36	Y
44389	3.12	3.02	Y
44390	3.84	3.74	Y
44391	4.22	4.12	Y
44392	3.63	3.53	Y
44394	4.13	4.03	Y
44401	4.44	4.34	Y
44402	4.80	4.70	Y
44403	5.60	5.50	Y
44404	3.12	3.02	Y
44405	3.33	3.23	Y
44406	4.20	4.10	Y
44407	5.06	4.96	Y
44408	4.24	4.14	Y
44500	0.49	0.39	Y
45303	1.50	1.40	Y
45305	1.25	1.15	Y
45307	1.70	1.60	Y
45308	1.40	1.30	Y
45309	1.50	1.40	Y
45315	1.80	1.70	Y
45317	2.00	1.90	Y
45320	1.78	1.68	Y
45321	1.75	1.65	Y
45327	2.00	1.90	Y
45332	1.86	1.76	Y
45333	1.65	1.55	Y
45334	2.10	2.00	Y
45335	1.14	1.04	Y
45337	2.20	2.10	Y
45338	2.15	2.05	Y
45340	1.35	1.25	Y
45341	2.22	2.12	Y
45342	3.08	2.98	Y
45346	2.91	2.81	Y
45347	2.82	2.72	Y
45349	3.62	3.52	Y
45350	1.78	1.68	Y
45378	3.36	3.26	Y
45378–53	1.68	1.63	Y
45379	4.38	4.28	Y
45380	3.66	3.56	Y
45381	3.66	3.56	Y
45382	4.76	4.66	Y
45384	4.17	4.07	Y
45385	4.67	4.57	Y
45386	3.87	3.77	Y
45388	4.98	4.88	Y
45389	5.34	5.24	Y
45390	6.14	6.04	Y
45391	4.74	4.64	Y
45392	5.60	5.50	Y
45393	4.78	4.68	Y
45398	4.30	4.20	Y
47000	1.90	1.65	N
47382	15.22	14.97	N
47383	9.13	8.88	N
47532	4.25	4.25	N
47533	6.00	5.38	N
47534	8.03	7.60	N
47535	4.50	3.95	N
47536	2.88	2.61	N
47538	6.60	4.75	N
47539	9.00	8.75	N
47540	10.75	9.03	N
47541	5.61	5.38	N
47542	2.50	2.85	N
47543	3.07	3.00	N
47544	4.29	3.28	N
49405	4.25	4.00	N
49406	4.25	4.00	N
49407	4.50	4.25	N
49411	3.82	3.57	N
49418	4.21	3.96	N
49440	4.18	3.93	N
49441	4.77	4.52	N
49442	4.00	3.75	N
49446	3.31	3.06	N
50200	2.63	2.38	N
50382	5.50	5.25	N
50384	5.00	4.75	N
50385	4.44	4.19	N
50386	3.30	3.05	N
50387	2.00	1.75	N
50430	3.15	2.90	N
50432	4.25	4.00	N
50433	5.30	5.05	N
50434	4.00	3.75	N
50592	6.80	6.55	N
50593	9.13	8.88	N
50606	3.16	3.16	N
50693	4.21	3.96	N
50694	5.50	5.25	N
50695	7.05	6.80	N
50705	4.03	4.03	N
50706	3.80	3.80	N
57155	5.40	5.15	N
66720	5.00	4.75	N
69300	6.69	6.44	N
77371	0.00	0.00	N
77600	1.56	1.31	N
77605	2.09	1.84	N
77610	1.56	1.31	N
77615	2.09	1.84	N
92920	10.10	9.85	N
92921	0.00	0.00	N
92924	11.99	11.74	N
92925	0.00	0.00	N
92928	11.21	10.96	N
92929	0.00	0.00	N
92933	12.54	12.29	N

TABLE 22—PROPOSED VALUATIONS FOR ENDOSCOPY SERVICES MINUS MODERATE SEDATION—Continued

HCPCS	CY 2016 work RVU	CY 2017 proposed work RVU	Use GMMM1 to report moderate sedation (Y/N)
92934	0.00	0.00	N
92937	11.20	10.95	N
92938	0.00	0.00	N
92941	12.56	12.31	N
92943	12.56	12.31	N
92944	0.00	0.00	N
92953	0.23	0.01	N
92960	2.25	2.00	N
92961	4.59	4.34	N
92973	3.28	3.28	N
92974	3.00	3.00	N
92975	7.24	6.99	N
92978	0.00	0.00	N
92979	0.00	0.00	N
92986	22.85	22.60	N
92987	23.63	23.38	N
93312	2.55	2.30	N
93313	0.51	0.26	N
93314	2.10	1.85	N
93315	2.94	2.69	N
93316	0.85	0.60	N
93317	2.09	1.84	N
93318	2.40	2.15	N
93451	2.72	2.47	N
93452	4.75	4.50	N
93453	6.24	5.99	N
93454	4.79	4.54	N
93455	5.54	5.29	N
93456	6.15	5.90	N
93457	6.89	6.64	N
93458	5.85	5.60	N
93459	6.60	6.35	N
93460	7.35	7.10	N
93461	8.10	7.85	N
93462	3.73	3.73	N
93463	2.00	2.00	N
93464	1.80	1.80	N
93505	4.37	4.12	N
93530	4.22	3.97	N
93561	0.50	0.25	N
93562	0.16	0.01	N
93563	1.11	1.11	N
93564	1.13	1.13	N
93565	0.86	0.86	N
93566	0.86	0.86	N
93567	0.97	0.97	N
93568	0.88	0.88	N
93571	0.00	0.00	N
93572	0.00	0.00	N
93582	12.56	12.31	N
93583	14.00	13.75	N
93609	0.00	0.00	N
93613	6.99	6.99	N
93615	0.99	0.74	N
93616	1.49	1.24	N
93618	4.25	4.00	N
93619	7.31	7.06	N
93620	11.57	11.32	N
93621	0.00	0.00	N
93622	0.00	0.00	N
93624	4.80	4.55	N
93640	3.51	3.26	N
93641	5.92	5.67	N
93642	4.88	4.63	N
93644	3.29	3.04	N
93650	10.49	10.24	N
93653	15.00	14.75	N
93654	20.00	19.75	N
93655	7.50	7.50	N
93656	20.02	19.77	N
93657	7.50	7.50	N
94011	2.00	1.75	N
94012	3.10	2.85	N
94013	0.66	0.41	N
96440	2.37	2.12	N
G0105	3.36	3.26	Y
G0105–53	1.68	1.63	Y
G0121	3.36	3.26	Y
G0121–53	1.68	1.63	Y
G0341	6.98	6.98	N

(38) Prolonged Evaluation and Management Services (CPT Codes 99354, 99358, and 99359)

We previously received RUC recommendations for face-to-face and non-face-to-face prolonged E/M services. In response to the CY 2016 PFS proposed rule, in which we sought comment about improving payment accuracy for cognitive services, commenters suggested that we consider making separate payment for CPT codes 99358 and 99359. As reflected in section II.E, we are proposing to make separate payment for these services.

We are also proposing values for services in this family of codes based on the RUC-recommended values, including for CPT code 99354, which would increase the current work RVU to 2.33. Likewise, we are proposing to adopt the RUC-recommended work values of 2.10 for CPT code 99358 and of 1.00 for CPT code 99359.

(39) Complex Chronic Care Management Services (CPT Codes 99487 and 99489)

We received RUC recommendations for CPT codes 99487 and 99489 following the October 2012 RUC meeting. For CY 2017, we are proposing to change the procedure status for CPT codes 99487 and 99489 from B (bundled) to A (active), see II.E, and are proposing to adopt the RUC-recommended values for work, 1.00 work RVUs for CPT code 99487 and 0.50 work RVUs for CPT code 99489, as well as direct PE inputs consistent with the RUC recommendations.

(40) Prostate Biopsy, Any Method (HCPCS Code G0416)

The College of American Pathologists and the American Society of Cytopathology formed an expert panel to make recommendations at the October 2015 RUC meeting to determine an appropriate work RVU for HCPCS code G0416, as they felt that the survey results were invalid. The panel made several arguments to the RUC in recommending for a higher work RVU under the RUC's "compelling evidence" standard. These arguments were: (1) That incorrect assumptions were made in previous valuations; (2) the value of HCPCS code G0416 remained constant while the code descriptors changed over the years; and (3) the "anomalous relationship" between HCPCS code G0416 and CPT code 88305 (Level IV—Surgical pathology, gross and microscopic examination). The expert panel recommended a work RVU of 4.00 based on a crosswalk from CPT code 38240 (Hematopoietic progenitor cell (HPC); allogeneic transplantation per donor). The RUC agreed.

We believe HCPCS code G0416 should not be valued as a direct crosswalk from CPT code 38240. Instead we believe CPT code 88305 is the basis for HCPCS code G0416, and therefore, HCPCS code G0416 should be valued as such. To value HCPCS code G0416, we used the intra-service time ratio between HCPCS code G0416 and CPT code 88305 to arrive at a work RVU of 3.60. To further support this method, we note that the IWPUT for HCPCS code G0416 with a work RVU of 3.60 is the same as CPT code 88305. Using the RUC recommended RVU of 4.00 results in a higher IWPUT, and we do not believe there is a difference in work intensity between these codes. Therefore for CY 2017, we are proposing a work RVU of 3.60 for HCPCS code G0416.

(41) Behavioral Health Integration: Psychiatric Collaborative Care Model (HCPCS Codes GPPP1, GPPP2, and GPPP3) and General Behavioral Health Integration (HCPCS Code GPPPX)

For CY 2017, we are proposing to establish and make separate Medicare payment using four new HCPCS G-codes, GPPP1 (Initial psychiatric collaborative care management, first 70 minutes in the first calendar month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional), GPPP2 (Subsequent psychiatric collaborative care management, first 60 minutes in a subsequent month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional), GPPP3 (Initial or subsequent psychiatric collaborative care management, each additional 30 minutes in a calendar month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional), and GPPPX (Care management services for behavioral health conditions, at least 20 minutes of clinical staff time, directed by a physician or other qualified health care professional time, per calendar month) for collaborative care and care management for beneficiaries with behavioral health conditions, as detailed in section II.E of this proposed rule. To value HCPCS codes GPPP1, GPPP2, and GPPP3, we are proposing to base the portion of the work RVU that accounts for the work of the treating physician or other qualified health care professional on a direct crosswalk to the proposed work values for the complex CCM codes, CPT codes 99487 and 99489. To value the portion of the work RVU that accounts for the psychiatric consultant, we are estimating ten minutes of psychiatric consultant time per patient per month and a value of 0.42 work RVUs, based on the per minute work RVUs for the highest volume codes typically billed by psychiatrists. Since the behavioral health care manager in the services described by HCPCS codes GPPP1, GPPP2, and GPPP3 should have academic with specialized training in behavioral health, we are proposing a new clinical labor type for the behavioral health care manager, L057B, at $0.57 per minute, based on the rates for genetic counselors in the direct PE input database. We are seeking comment on all aspects of these proposed valuations.

To value HCPCS code GPPPX, we are proposing a work value based on a direct crosswalk from CPT code 99490 (Chronic care management services), a work value of 0.61 RVUs. We recognize that the services described by CPT code 99490 are distinct from those furnished under the CoCM and we believe that these alsovary based on different kinds of BHI care. We note that there are relatively few existing codes that describe these kinds of services over a calendar month. We also believe that the resources associated with 99490 may vary based on the ways different practitioners implement the service. Until we have more information about how these services are typically furnished, we believe valuation based on the minimum resources would be most appropriate. To account for the care manager minutes in the direct PE inputs for HCPCS code GPPPX, we are proposing to use clinical labor type L045C, which is the labor type for social workers/psychologists and has a rate of $0.45 per minute.

(42) Resource-Intensive Services (HCPCS Code GDDD1)

As discussed in section II.E, we are proposing to establish payment for services furnished to patients with mobility-related disabilities, through a new add-on G-code, to be billable with office/outpatient E/M and TCM codes. Based on our analysis of the resources typically involved in furnishing office visits to patients with these needs (especially including the typical additional practitioner and staff time), we believe that the physician work and time for HCPCS code GDDD1 is most accurately valued through a direct crosswalk from CPT code 99212 (Level 2 office or other outpatient visit for the evaluation and management of an established patient). Therefore, we are proposing a work RVU of 0.48 and a physician time of 16 minutes for HCPCS code GDDD1. We are seeking comment on whether these work and time values accurately capture the additional physician work typically involved in furnishing services to patients with mobility impairments.

We believe that a direct crosswalk to the clinical staff-time associated with CPT code 99212, which is 27 minutes of LN/LPN/MTA (L037D) accurately represents the additional clinical staff time required to furnish an outpatient office visit or TCM to a patient with a mobility-related disability. We are also proposing to include as direct practice expense inputs 27 minutes for a stretcher (EF018) and a high/low table (EF028), and 27 minutes for new equipment inputs associated with the following: A patient lift system, wheelchair accessible scale, and padded leg support positioning system. These items are included in the CY 2017 proposed direct PE input database. We are seeking comments on whether these inputs are appropriate, and whether any additional inputs are typically used in treating patients with mobility-impairments.

(43) Comprehensive Assessment and Care Planning for Patients With Cognitive Impairment (HCPCS Code GPPP6)

For CY 2017, we are proposing to create and pay separately for new HCPCS code GPPP6 (Cognition and functional assessment using standardized instruments with development of recorded care plan for the patient with cognitive impairment, history face-to-face obtained from patient and/or caregiver, in office or other outpatient setting or home or domiciliary or rest home), see II.E for further discussion. Based on similarities between work intensity and time, we believe that the physician work and time for this code would be accurately valued by combining the work RVUs from CPT code 99204 (Level 4 office or other outpatient visit for the evaluation and management of a new patient) and half the work RVUs for HCPCS code G0181 (Physician supervision of a patient receiving Medicare-covered services furnished by a participating home health agency (patient not present) requiring complex and multidisciplinary care modalities involving regular physician development and/or revision of care plans, review of subsequent reports of patient status, review of laboratory and other studies, communication (including telephone calls) with other health care professionals involved in the patient's care, integration of new information into the medical treatment plan and/or adjustment of medical therapy, within a calendar month, 30 minutes or more). Therefore, we are proposing a work RVU of 3.30. For direct practice expense inputs we are proposing 70 total minutes of time for RN/LPN/MTA (L037D). We believe this is typical based on information from several specialty societies representing practitioners who typically furnish this service and report, it, when appropriate, using E/M codes. We are seeking comment on these valuation assumptions and would welcome additional information on the work and direct practice expense associated with furnishing this service.

(44) Comprehensive Assessment and Care Planning for Patients Requiring Chronic Care Management (HCPCS Code GPPP7)

For CY 2017 we are proposing to make payment for the resource costs of comprehensive assessment and care planning for patients requiring CCM services through HCPCS code GPPP7 as an add-on code to be billed with the initiating visit for CCM for patients that require extensive assessment and care planning (see section II.E). In valuing this code, we believe that a crosswalk to half the work and time values of HCPCS code G0181 (Physician supervision of a patient receiving Medicare-covered services provided by a participating home health agency (patient not present) requiring complex and multidisciplinary care modalities involving regular physician development and/or revision of care plans, review of subsequent reports of patient status, review of laboratory and other studies, communication (including telephone calls) with other health care professionals involved in the patient's care, integration of new information into the medical treatment plan and/or adjustment of medical therapy, within a calendar month, 30 minutes or more) accurately accounts for the time and intensity of the work associated with furnishing this service over and above the work accounted for as part of the separately billed initiating visit. Therefore, we are proposing a work RVU of 0.87 and 29 minutes of physician time. We are also proposing 36 minutes for a RN/LPN/MTA (L037D) as the only direct PE input for this service.

(45) Telehealth Consultation for a Patient Requiring Critical Care Services (HCPCS Codes GTTT1 and GTTT2)

As discussed in section II.C, we are proposing use of HCPCS G-codes, GTTT1 (Telehealth consultation, critical care, physicians typically spend 60 minutes communicating with the patient via telehealth (initial) and GTTT2 (Telehealth consultation, critical care, physicians typically spend 50 minutes communicating with the patient via telehealth (subsequent)), to report telehealth consultations for a patient requiring critical care services. We note that due to limited coding granularity for high-intensity cognitive services, in the PFS, we do not believe there is an intuitive crosswalk code for ideal estimation of the work and time values for GTTT1. In general, we believe that the overall work for GTTT1 is not as much as 99291 (Critical care, evaluation and management of the critically ill or critically injured patient; first 30–74 minutes) but that the service involves more work than G0427 (Telehealth consultation, emergency department or initial inpatient, typically 70 minutes or more communicating with the patient via telehealth). We believe that GTTT1 is most accurately valued by a crosswalk to the work RVU and physician intra-service time of 38240 (Hematopoietic progenitor cell (HPC); allogeneic transplantation per donor) can therefore serve as an appropriate crosswalk. Therefore we are proposing a work RVU of 4.0 and are seeking comment on the accuracy of these assumptions. We do not believe that direct PE inputs would typically be involved with furnishing this service from the distant site. For GTTT2 we are proposing a work RVU of 3.86 based on a crosswalk from G0427. We believe that G0427 has similar overall work intensity to GTTT2 and has a similar intraservice time. We also believe that no direct PE inputs would typically be associated with furnishing this service from the distant site.

TABLE 23—PROPOSED CY 2017 WORK RVUS FOR NEW, REVISED AND POTENTIALLY MISVALUED CODES

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
00740	Anesthesia for upper gastrointestinal endoscopic procedures, endoscope introduced proximal to duodenum.	0.00	0.00	0.00	No.
00810	Anesthesia for lower intestinal endoscopic procedures, endoscope introduced distal to duodenum.	0.00	0.00	0.00	No.
10035	Placement of soft tissue localization device(s) (*e.g.,* clip, metallic pellet, wire/needle, radioactive seeds), percutaneous, including imaging guidance; first lesion.	1.70		1.70	No.
10036	Placement of soft tissue localization device(s) (*e.g.,* clip, metallic pellet, wire/needle, radioactive seeds), percutaneous, including imaging guidance; each additional lesion.	0.85		0.85	No.
11730	Avulsion of nail plate, partial or complete, simple; single	1.10	1.10	1.05	No.
11732	Avulsion of nail plate, partial or complete, simple; each additional nail plate.	0.44	0.44	0.38	Yes.
20245	Biopsy, bone, open; deep (*e.g.,* humerus, ischium, femur)	8.95	6.50	6.00	No.
20550	Injection(s); single tendon sheath, or ligament, aponeurosis (*e.g.,* plantar "fascia").	0.75	0.75	0.75	No.
20552	Injection(s); single or multiple trigger point(s), 1 or 2 muscle(s).	0.66	0.66	0.66	No.
20553	Injection(s); single or multiple trigger point(s), 3 or more muscles.	0.75	0.75	0.75	No.
228X1	Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; single level.	NEW	15.00	13.50	No.
228X2	Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; second level.	NEW	4.00	4.00	No.
228X4	Insertion of interlaminar/interspinous process stabilization/distraction device, without open decompression or fusion, including image guidance when performed, lumbar; single level.	NEW	7.39	7.03	No.
228X5	Insertion of interlaminar/interspinous process stabilization/distraction device, without open decompression or fusion, including image guidance when performed, lumbar; second level.	NEW	2.34	2.34	No.

TABLE 23—PROPOSED CY 2017 WORK RVUS FOR NEW, REVISED AND POTENTIALLY MISVALUED CODES—Continued

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
22X81	Insertion of interbody biomechanical device(s) (*e.g.*, synthetic cage, mesh) with integral anterior instrumentation for device anchoring (*e.g.*, screws, flanges) when performed to intervertebral disc space in conjunction with interbody arthrodesis, each interspace.	NEW	4.88	4.25	No.
22X82	Insertion of intervertebral biomechanical device(s) (*e.g.*, synthetic cage, mesh) with integral anterior instrumentation for device anchoring (*e.g.*, screws, flanges) when performed to vertebral corpectomy(ies) (vertebral body resection, partial or complete) defect, in conjunction with interbody arthrodesis, each contiguous defect.	NEW	5.50	5.50	No.
22X83	Insertion of intervertebral biomechanical device(s) (*e.g.*, synthetic cage, mesh, methylmethacrylate) to intervertebral disc space or vertebral body defect without interbody arthrodesis, each contiguous defect.	NEW	6.00	5.50	No.
26356	Repair or advancement, flexor tendon, in zone 2 digital flexor tendon sheath (*e.g.*, no man's land); primary, without free graft, each tendon.	9.56		9.56	No.
26357	Repair or advancement, flexor tendon, in zone 2 digital flexor tendon sheath (*e.g.*, no man's land); secondary, without free graft, each tendon.	10.53		11.00	No.
26358	Repair or advancement, flexor tendon, in zone 2 digital flexor tendon sheath (*e.g.*, no man's land); secondary, with free graft (includes obtaining graft), each tendon.	12.13		12.60	No.
271X1	Closed treatment of posterior pelvic ring fracture(s), dislocation(s), diastasis or subluxation of the ilium, sacroiliac joint, and/or sacrum, with or without anterior pelvic ring fracture(s) and/or dislocation(s) of the pubic symphysis and/or superior/inferior rami, unilateral or bilateral; without manipulation.	NEW	5.50	1.53	Yes.
271X2	Closed treatment of posterior pelvic ring fracture(s), dislocation(s), diastasis or subluxation of the ilium, sacroiliac joint, and/or sacrum, with or without anterior pelvic ring fracture(s) and/or dislocation(s) of the pubic symphysis and/or superior/inferior rami, unilateral or bilateral; with manipulation, requiring more than local anesthesia (*i.e.*, general anesthesia, moderate sedation, spinal/epidural).	NEW	9.00	4.75	Yes.
28289	Hallux rigidus correction with cheilectomy, debridement and capsular release of the first metatarsophalangeal joint.	8.31	6.90	6.90	No.
28292	Correction, hallux valgus (bunion), with or without sesamoidectomy; Keller, McBride, or Mayo type procedure.	9.05	7.44	7.44	No.
28296	Correction, hallux valgus (bunion), with or without sesamoidectomy; with metatarsal osteotomy (*e.g.*, Mitchell, Chevron, or concentric type procedures).	8.35	8.25	8.25	No.
28297	Correction, hallux valgus (bunion), with or without sesamoidectomy; Lapidus-type procedure.	9.43	9.29	9.29	No.
28298	Correction, hallux valgus (bunion), with or without sesamoidectomy; by phalanx osteotomy.	8.13	7.75	7.75	No.
28299	Correction, hallux valgus (bunion), with or without sesamoidectomy; by double osteotomy.	11.57	9.29	9.29	No.
282X1	Hallux rigidus correction with cheilectomy, debridement and capsular release of the first metatarsophalangeal joint; with implant.	NEW	8.01	7.81	No.
282X2	Correction, hallux valgus (bunionectomy), with sesamoidectomy, when performed; with proximal metatarsal osteotomy, any method.	NEW	8.57	8.25	No.
31500	Intubation, endotracheal, emergency procedure	2.33	3.00	2.66	No.
31575	Laryngoscopy, flexible fiberoptic; diagnostic	1.10	1.00	0.94	No.
31576	Laryngoscopy, flexible fiberoptic; with biopsy	1.97	1.95	1.89	No.
31577	Laryngoscopy, flexible fiberoptic; with removal of foreign body.	2.47	2.25	2.19	No.
31578	Laryngoscopy, flexible fiberoptic; with removal of lesion	2.84	2.49	2.43	No.
31579	Laryngoscopy, flexible or rigid fiberoptic, with stroboscopy	2.26	1.94	1.88	No.
317X1	Laryngoscopy, flexible; with ablation or destruction of lesion(s) with laser, unilateral.	NEW	3.07	3.01	No.

TABLE 23—PROPOSED CY 2017 WORK RVUS FOR NEW, REVISED AND POTENTIALLY MISVALUED CODES—Continued

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
317X2	Laryngoscopy, flexible; with therapeutic injection(s) (*e.g.*, chemodenervation agent or corticosteroid, injected percutaneous, transoral, or via endoscope channel), unilateral.	NEW	2.49	2.43	No.
317X3	Laryngoscopy, flexible; with injection(s) for augmentation (*e.g.*, percutaneous, transoral), unilateral.	NEW	2.49	2.43	No.
31580	Laryngoplasty; for laryngeal web, 2-stage, with keel insertion and removal.	14.66	14.60	14.60	No.
31584	Laryngoplasty; with open reduction of fracture	20.47	20.00	17.58	No.
31587	Laryngoplasty, cricoid split	15.27	15.27	15.27	No.
315X1	Laryngoplasty; for laryngeal stenosis, with graft, without indwelling stent placement, younger than 12 years of age.	NEW	21.50	21.50	No.
315X2	Laryngoplasty; for laryngeal stenosis, with graft, without indwelling stent placement, age 12 years or older.	NEW	20.50	20.50	No.
315X3	Laryngoplasty; for laryngeal stenosis, with graft, with indwelling stent placement, younger than 12 years of age.	NEW	22.00	22.00	No.
315X4	Laryngoplasty; for laryngeal stenosis, with graft, with indwelling stent placement, age 12 years or older.	NEW	22.00	22.00	No.
315X5	Laryngoplasty, medialization; unilateral	NEW	15.60	13.56	No.
315X6	Cricotracheal resection	NEW	25.00	25.00	No.
333X3	Percutaneous transcatheter closure of the left atrial appendage with endocardial implant, including fluoroscopy, transseptal puncture, catheter placement(s), left atrial angiography, left atrial appendage angiography, when performed, and radiological supervision and interpretation.	NEW	14.00	13.00	No.
334X1	Valvuloplasty, aortic valve, open, with cardiopulmonary bypass; simple (*i.e.*, valvotomy, debridement, debulking and/or simple commissural resuspension).	NEW	35.00	35.00	No.
334X2	Valvuloplasty, aortic valve, open, with cardiopulmonary bypass; complex (*e.g.*, leaflet extension, leaflet resection, leaflet reconstruction or annuloplasty).	NEW	44.00	41.50	No.
364X1	Partial exchange transfusion, blood, plasma or crystalloid necessitating the skill of a physician or other qualified health care professional, newborn.	NEW	2.00	2.00	No.
36440	Push transfusion, blood, 2 years or younger	1.03	1.03	1.03	No.
36450	Exchange transfusion, blood; newborn	2.23	3.50	3.50	No.
36455	Exchange transfusion, blood; other than newborn	2.43	2.43	2.43	No.
36X41	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, mechanochemical; first vein treated.	NEW	3.50	3.50	No.
364X2	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, mechanochemical; subsequent vein(s) treated in a single extremity, each through separate access sites.	NEW	2.25	1.75	No.
369X1	Introduction of needle(s) and/or catheter(s), dialysis circuit, with diagnostic angiography of the dialysis circuit, including all direct puncture(s) and catheter placement(s), injection(s) of contrast, all necessary imaging from the arterial anastomosis and adjacent artery through entire venous outflow including the inferior or superior vena cava, fluoroscopic guidance, radiologic supervision and interpretation and image documentation and report.	NEW	3.36	2.82	No.
369X2	Introduction of needle(s) and/or catheter(s), dialysis circuit, with diagnostic angiography of the dialysis circuit, including all direct puncture(s) and catheter placement(s), injection(s) of contrast, all necessary imaging from the arterial anastomosis and adjacent artery through entire venous outflow including the inferior or superior vena cava, fluoroscopic guidance, radiologic supervision and interpretation and image documentation and report; with transluminal balloon angioplasty, peripheral dialysis segment, including all imaging and radiological supervision and interpretation necessary to perform the angioplasty.	NEW	4.83	4.24	No.

TABLE 23—PROPOSED CY 2017 WORK RVUS FOR NEW, REVISED AND POTENTIALLY MISVALUED CODES—Continued

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
369X3	Introduction of needle(s) and/or catheter(s), dialysis circuit, with diagnostic angiography of the dialysis circuit, including all direct puncture(s) and catheter placement(s), injection(s) of contrast, all necessary imaging from the arterial anastomosis and adjacent artery through entire venous outflow including the inferior or superior vena cava, fluoroscopic guidance, radiologic supervision and interpretation and image documentation and report; with transcatheter placement of intravascular stent(s) peripheral dialysis segment, including all imaging and radiological supervision and interpretation necessary to perform the stenting, and all angioplasty within the peripheral dialysis segment.	NEW	6.39	5.85	No.
369X4	Percutaneous transluminal mechanical thrombectomy and/or infusion for thrombolysis, dialysis circuit, any method, including all imaging and radiological supervision and interpretation, diagnostic angiography, fluoroscopic guidance, catheter placement(s), and intraprocedural pharmacological thrombolytic injection(s).	NEW	7.50	6.73	No.
369X5	Percutaneous transluminal mechanical thrombectomy and/or infusion for thrombolysis, dialysis circuit, any method, including all imaging and radiological supervision and interpretation, diagnostic angiography, fluoroscopic guidance, catheter placement(s), and intraprocedural pharmacological thrombolytic injection(s); with transluminal balloon angioplasty, peripheral dialysis segment, including all imaging and radiological supervision and interpretation necessary to perform the angioplasty.	NEW	9.00	8.46	No.
369X6	Percutaneous transluminal mechanical thrombectomy and/or infusion for thrombolysis, dialysis circuit, any method, including all imaging and radiological supervision and interpretation, diagnostic angiography, fluoroscopic guidance, catheter placement(s), and intraprocedural pharmacological thrombolytic injection(s); with transcatheter placement of an intravascular stent(s), peripheral dialysis segment, including all imaging and radiological supervision and interpretation to perform the stenting and all angioplasty within the peripheral dialysis circuit.	NEW	10.42	9.88	No.
369X7	Transluminal balloon angioplasty, central dialysis segment, performed through dialysis circuit, including all imaging and radiological supervision and interpretation required to perform the angioplasty.	NEW	3.00	2.48	No.
369X8	Transcatheter placement of an intravascular stent(s), central dialysis segment, performed through dialysis circuit, including all imaging and radiological supervision and interpretation required to perform the stenting, and all angioplasty in the central dialysis segment.	NEW	4.25	3.73	No.
369X9	Dialysis circuit permanent vascular embolization or occlusion (including main circuit or any accessory veins), endovascular, including all imaging and radiological supervision and interpretation necessary to complete the intervention.	NEW	4.12	3.48	No.
372X1	Transluminal balloon angioplasty (except lower extremity artery(s) for occlusive disease, intracranial, coronary, pulmonary, or dialysis circuit), open or percutaneous, including all imaging and radiological supervision and interpretation necessary to perform the angioplasty within the same artery; initial artery.	NEW	7.00	7.00	No.
372X2	Transluminal balloon angioplasty (except lower extremity artery(s) for occlusive disease, intracranial, coronary, pulmonary, or dialysis circuit), open or percutaneous, including all imaging and radiological supervision and interpretation necessary to perform the angioplasty within the same artery; each additional artery.	NEW	3.50	3.50	No.
372X3	Transluminal balloon angioplasty (except dialysis circuit), open or percutaneous, including all imaging and radiological supervision and interpretation necessary to perform the angioplasty within the same vein; initial vein.	NEW	6.00	6.00	No.

TABLE 23—PROPOSED CY 2017 WORK RVUS FOR NEW, REVISED AND POTENTIALLY MISVALUED CODES—Continued

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
372X4	Transluminal balloon angioplasty (except dialysis circuit), open or percutaneous, including all imaging and radiological supervision and interpretation necessary to perform the angioplasty within the same vein; each additional vein.	NEW	2.97	2.97	No.
41530	Submucosal ablation of the tongue base, radiofrequency, 1 or more sites, per session.	3.50		3.50	No.
43210	Esophagogastroduodenoscopy, flexible, transoral; with esophagogastric fundoplasty, partial or complete, includes duodenoscopy when performed.	7.75		7.75	No.
432X1	Laparoscopy, surgical, esophageal sphincter augmentation procedure, placement of sphincter augmentation device (*i.e.,* magnetic band), including cruroplasty when performed.	NEW	10.13	9.03	No.
432X2	Removal of esophageal sphincter augmentation device	NEW	10.47	9.37	No.
47531	Injection procedure for cholangiography, percutaneous, complete diagnostic procedure including imaging guidance (*e.g.,* ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation; existing access.	1.80	1.30	1.30	No.
47532	Injection procedure for cholangiography, percutaneous, complete diagnostic procedure including imaging guidance (*e.g.,* ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation; new access (*e.g.,* percutaneous transhepatic cholangiogram).	4.25	4.32	4.25	No.
47533	Placement of biliary drainage catheter, percutaneous, including diagnostic cholangiography when performed, imaging guidance (*e.g.,* ultrasound and/or fluoroscopy), and all associated radiological supervision and interpretation; external.	6.00	5.45	5.38	No.
47534	Placement of biliary drainage catheter, percutaneous, including diagnostic cholangiography when performed, imaging guidance (*e.g.,* ultrasound and/or fluoroscopy), and all associated radiological supervision and interpretation; internal-external.	8.03	7.67	7.60	No.
47535	Conversion of external biliary drainage catheter to internal-external biliary drainage catheter, percutaneous, including diagnostic cholangiography when performed, imaging guidance (*e.g.,* fluoroscopy), and all associated radiological supervision and interpretation.	4.50	4.02	3.95	No.
47536	Exchange of biliary drainage catheter (*e.g.,* external, internal-external, or conversion of internal-external to external only), percutaneous, including diagnostic cholangiography when performed, imaging guidance (*e.g.,* fluoroscopy), and all associated radiological supervision and interpretation.	2.88	2.68	2.61	No.
47537	Removal of biliary drainage catheter, percutaneous, requiring fluoroscopic guidance (*e.g.,* with concurrent indwelling biliary stents), including diagnostic cholangiography when performed, imaging guidance (*e.g.,* fluoroscopy), and all associated radiological supervision and interpretation.	1.83	1.84	1.84	No.
47538	Placement of stent(s) into a bile duct, percutaneous, including diagnostic cholangiography, imaging guidance (*e.g.,* fluoroscopy and/or ultrasound), balloon dilation, catheter exchange(s) and catheter removal(s) when performed, and all associated radiological supervision and interpretation, each stent; existing access.	6.60	4.82	4.75	No.
47539	Placement of stent(s) into a bile duct, percutaneous, including diagnostic cholangiography, imaging guidance (*e.g.,* fluoroscopy and/or ultrasound), balloon dilation, catheter exchange(s) and catheter removal(s) when performed, and all associated radiological supervision and interpretation, each stent; new access, without placement of separate biliary drainage catheter.	9.00	8.82	8.75	No.

Table 23—Proposed CY 2017 Work RVUs for New, Revised and Potentially Misvalued Codes—Continued

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
47540	Placement of stent(s) into a bile duct, percutaneous, including diagnostic cholangiography, imaging guidance (*e.g.,* fluoroscopy and/or ultrasound), balloon dilation, catheter exchange(s) and catheter removal(s) when performed, and all associated radiological supervision and interpretation, each stent; new access, with placement of separate biliary drainage catheter (*e.g.,* external or internal-external).	10.75	9.10	9.03	No.
47541	Placement of access through the biliary tree and into small bowel to assist with an endoscopic biliary procedure (*e.g.,* rendezvous procedure), percutaneous, including diagnostic cholangiography when performed, imaging guidance (*e.g.,* ultrasound and/or fluoroscopy), and all associated radiological supervision and interpretation, new access.	5.61	6.82	5.38	No.
47542	Balloon dilation of biliary duct(s) or of ampulla (sphincteroplasty), percutaneous, including imaging guidance (*e.g.,* fluoroscopy), and all associated radiological supervision and interpretation, each duct.	2.50	2.85	2.85	No.
47543	Endoluminal biopsy(ies) of biliary tree, percutaneous, any method(s) (*e.g.,* brush, forceps, and/or needle), including imaging guidance (*e.g.,* fluoroscopy), and all associated radiological supervision and interpretation, single or multiple.	3.07	3.00	3.00	No.
47544	Removal of calculi/debris from biliary duct(s) and/or gallbladder, percutaneous, including destruction of calculi by any method (*e.g.,* mechanical, electrohydraulic, lithotripsy) when performed, imaging guidance (*e.g.,* fluoroscopy), and all associated radiological supervision and interpretation.	4.29	3.28	3.28	No.
49185	Sclerotherapy of a fluid collection (*e.g.,* lymphocele, cyst, or seroma), percutaneous, including contrast injection(s), sclerosant injection(s), diagnostic study, imaging guidance (*e.g.,* ultrasound, fluoroscopy) and radiological supervision and interpretation when performed.	2.35		2.35	No.
50606	Endoluminal biopsy of ureter and/or renal pelvis, nonendoscopic, including imaging guidance (*e.g.,* ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation.	3.16		3.16	No.
50705	Ureteral embolization or occlusion, including imaging guidance (*e.g.,* ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation.	4.03		4.03	No.
50706	Balloon dilation, ureteral stricture, including imaging guidance (*e.g.,* ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation.	3.80		3.80	No.
51700	Bladder irrigation, simple, lavage and/or instillation	0.88	0.60	0.60	No.
51701	Insertion of non-indwelling bladder catheter (*e.g.,* straight catheterization for residual urine).	0.50	0.50	0.50	No.
51702	Insertion of temporary indwelling bladder catheter; simple (*e.g.,* Foley).	0.50	0.50	0.50	No.
51703	Insertion of temporary indwelling bladder catheter; complicated (*e.g.,* altered anatomy, fractured catheter/balloon).	1.47	1.47	1.47	No.
51720	Bladder instillation of anticarcinogenic agent (including retention time).	1.50	0.87	0.87	No.
51784	Electromyography studies (EMG) of anal or urethral sphincter, other than needle, any technique.	1.53	0.75	0.75	No.
52000	Cystourethroscopy (separate procedure)	2.23	1.75	1.53	No.
55700	Biopsy, prostate; needle or punch, single or multiple, any approach.	2.58	2.50	2.06	No.
55866	Laparoscopy, surgical prostatectomy, retropubic radical, including nerve sparing, includes robotic assistance, when performed.	21.36		21.36	No.
58555	Hysteroscopy, diagnostic (separate procedure)	3.33	3.07	2.65	No.
58558	Hysteroscopy, surgical; with sampling (biopsy) of endometrium and/or polypectomy, with or without D & C.	4.74	4.37	4.17	No.
58559	Hysteroscopy, surgical; with lysis of intrauterine adhesions (any method).	6.16	5.54	5.20	No.
58560	Hysteroscopy, surgical; with division or resection of intrauterine septum (any method).	6.99	6.15	5.75	No.
58561	Hysteroscopy, surgical; with removal of leiomyomata	9.99	7.00	6.60	No.

TABLE 23—PROPOSED CY 2017 WORK RVUS FOR NEW, REVISED AND POTENTIALLY MISVALUED CODES—Continued

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
58562	Hysteroscopy, surgical; with removal of impacted foreign body.	5.20	4.17	4.00	No.
58563	Hysteroscopy, surgical; with endometrial ablation (*e.g.*, endometrial resection, electrosurgical ablation, thermoablation).	6.16	4.62	4.47	No.
585X1	Laparoscopy, surgical, ablation of uterine fibroid(s) including intraoperative ultrasound guidance and monitoring, radiofrequency.	NEW	14.08	14.08	No.
61640	Balloon dilatation of intracranial vasospasm, percutaneous; initial vessel.	N	N	N	No.
61641	Balloon dilatation of intracranial vasospasm, percutaneous; each additional vessel in same vascular family.	N	N	N	No.
61642	Balloon dilatation of intracranial vasospasm, percutaneous; each additional vessel in different vascular family.	N	N	N	No.
61645	Percutaneous arterial transluminal mechanical thrombectomy and/or infusion for thrombolysis, intracranial, any method, including diagnostic angiography, fluoroscopic guidance, catheter placement, and intraprocedural pharmacological thrombolytic injection(s).	15.00		15.00	No.
61650	Endovascular intracranial prolonged administration of pharmacologic agent(s) other than for thrombolysis, arterial, including catheter placement, diagnostic angiography, and imaging guidance; initial vascular territory.	10.00		10.00	No.
61651	Endovascular intracranial prolonged administration of pharmacologic agent(s) other than for thrombolysis, arterial, including catheter placement, diagnostic angiography, and imaging guidance; each additional vascular territory.	4.25		4.25	No.
623X5	Injection(s), of diagnostic or therapeutic substance(s) (*e.g.*, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, interlaminar epidural or subarachnoid, cervical or thoracic; without imaging guidance.	NEW	1.80	1.80	No.
623X6	Injection(s), of diagnostic or therapeutic substance(s) (*e.g.*, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, interlaminar epidural or subarachnoid, cervical or thoracic; with imaging guidance (*i.e.*, fluoroscopy or CT).	NEW	1.95	1.95	No.
623X7	Injection(s), of diagnostic or therapeutic substance(s) (*e.g.*, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, interlaminar epidural or subarachnoid, lumbar or sacral (caudal); without imaging guidance.	NEW	1.55	1.55	No.
623X8	Injection(s), of diagnostic or therapeutic substance(s) (*e.g.*, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, interlaminar epidural or subarachnoid, lumbar or sacral (caudal); with imaging guidance (ie, fluoroscopy or CT).	NEW	1.80	1.80	No.
623X9	Injection(s), including indwelling catheter placement, continuous infusion or intermittent bolus, of diagnostic or therapeutic substance(s) (*e.g.*, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, interlaminar epidural or subarachnoid, cervical or thoracic; without imaging guidance.	NEW	1.89	1.89	No.
62X10	Injection(s), including indwelling catheter placement, continuous infusion or intermittent bolus, of diagnostic or therapeutic substance(s) (*e.g.*, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, interlaminar epidural or subarachnoid, cervical or thoracic; with imaging guidance (ie, fluoroscopy or CT).	NEW	2.20	2.20	No.

TABLE 23—PROPOSED CY 2017 WORK RVUS FOR NEW, REVISED AND POTENTIALLY MISVALUED CODES—Continued

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
62X11	Injection(s), including indwelling catheter placement, continuous infusion or intermittent bolus, of diagnostic or therapeutic substance(s) (*e.g.,* anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, interlaminar epidural or subarachnoid, lumbar or sacral (caudal); without imaging guidance.	NEW	1.78	1.78	No.
62X12	Injection(s), including indwelling catheter placement, continuous infusion or intermittent bolus, of diagnostic or therapeutic substance(s) (*e.g.,* anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, interlaminar epidural or subarachnoid, lumbar or sacral (caudal); with imaging guidance (ie, fluoroscopy or CT).	NEW	1.90	1.90	No.
630X1	Endoscopic decompression of spinal cord, nerve root(s), including laminotomy, partial facetectomy, foraminotomy, discectomy and/or excision of herniated intervertebral disc; 1 interspace, lumbar.	NEW	10.47	9.09	No.
64461	Paravertebral block (PVB) (paraspinous block), thoracic; single injection site (includes imaging guidance, when performed).	1.75		1.75	No.
64462	Paravertebral block (PVB) (paraspinous block), thoracic; second and any additional injection site(s) (includes imaging guidance, when performed).	1.10		1.10	No.
64463	Paravertebral block (PVB) (paraspinous block), thoracic; continuous infusion by catheter (includes imaging guidance, when performed).	1.81		1.81	No.
64553	Percutaneous implantation of neurostimulator electrode array; cranial nerve.	2.36		2.36	Yes.
64555	Percutaneous implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve).	2.32		2.32	Yes.
64566	Posterior tibial neurostimulation, percutaneous needle electrode, single treatment, includes programming.	0.60		0.60	No.
65778	Placement of amniotic membrane on the ocular surface; without sutures.	1.00		1.00	No.
65779	Placement of amniotic membrane on the ocular surface; single layer, sutured.	2.50		2.50	No.
65780	Ocular surface reconstruction; amniotic membrane transplantation, multiple layers.	7.81		7.81	No.
65855	Trabeculoplasty by laser surgery	2.66		2.77	No.
66170	Fistulization of sclera for glaucoma; trabeculectomy ab externo in absence of previous surgery.	11.27		11.27	No.
66172	Fistulization of sclera for glaucoma; trabeculectomy ab externo with scarring from previous ocular surgery or trauma (includes injection of antifibrotic agents).	12.57		12.57	No.
67101	Repair of retinal detachment, 1 or more sessions; cryotherapy or diathermy, including drainage of subretinal fluid, when performed.	8.80	3.50	3.50	No.
67105	Repair of retinal detachment, 1 or more sessions; photocoagulation, including drainage of subretinal fluid, when performed.	8.53	3.84	3.39	No.
67107	Repair of retinal detachment; scleral buckling (such as lamellar scleral dissection, imbrication or encircling procedure), including, when performed, implant, cryotherapy, photocoagulation, and drainage of subretinal fluid.	14.06		14.06	No.
67108	Repair of retinal detachment; with vitrectomy, any method, including, when performed, air or gas tamponade, focal endolaser photocoagulation, cryotherapy, drainage of subretinal fluid, scleral buckling, and/or removal of lens by same technique.	15.19		15.19	No.
67110	Repair of retinal detachment; by injection of air or other gas (*e.g.,* pneumatic retinopexy).	8.31		8.31	No.
67113	Repair of complex retinal detachment (*e.g.,* proliferative vitreoretinopathy, stage C–1 or greater, diabetic traction retinal detachment, retinopathy of prematurity, retinal tear of greater than 90 degrees), with vitrectomy and membrane peeling, including, when performed, air, gas, or silicone oil tamponade, cryotherapy, endolaser photocoagulation, drainage of subretinal fluid, scleral buckling, and/or removal of lens.	19.00		19.00	No.

TABLE 23—PROPOSED CY 2017 WORK RVUS FOR NEW, REVISED AND POTENTIALLY MISVALUED CODES—Continued

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
67227	Destruction of extensive or progressive retinopathy (*e.g.*, diabetic retinopathy), cryotherapy, diathermy.	3.50		3.50	No.
67228	Treatment of extensive or progressive retinopathy (*e.g.*, diabetic retinopathy), photocoagulation.	4.39		4.39	No.
70540	Magnetic resonance (*e.g.*, proton) imaging, orbit, face, and/or neck; without contrast material(s).	1.35	1.35	1.35	No.
70542	Magnetic resonance (*e.g.*, proton) imaging, orbit, face, and/or neck; with contrast material(s).	1.62	1.62	1.62	No.
70543	Magnetic resonance (*e.g.*, proton) imaging, orbit, face, and/or neck; without contrast material(s), followed by contrast material(s) and further sequences.	2.15	2.15	2.15	No.
72170	Radiologic examination, pelvis; 1 or 2 views	0.17		0.17	No.
73501	Radiologic examination, hip, unilateral, with pelvis when performed; 1 view.	0.18		0.18	No.
73502	Radiologic examination, hip, unilateral, with pelvis when performed; 2–3 views.	0.22		0.22	No.
73503	Radiologic examination, hip, unilateral, with pelvis when performed; minimum of 4 views.	0.27		0.27	No.
73521	Radiologic examination, hips, bilateral, with pelvis when performed; 2 views.	0.22		0.22	No.
73522	Radiologic examination, hips, bilateral, with pelvis when performed; 3–4 views.	0.29		0.29	No.
73523	Radiologic examination, hips, bilateral, with pelvis when performed; minimum of 5 views.	0.31		0.31	No.
73551	Radiologic examination, femur; 1 view	0.16		0.16	No.
73552	Radiologic examination, femur; minimum 2 views	0.18		0.18	No.
74712	Magnetic resonance (*e.g.*, proton) imaging, fetal, including placental and maternal pelvic imaging when performed; single or first gestation.	3.00		3.00	No.
74713	Magnetic resonance (*e.g.*, proton) imaging, fetal, including placental and maternal pelvic imaging when performed; each additional gestation.	1.78		1.85	No.
767X1	Ultrasound, abdominal aorta, real time with image documentation, screening study for abdominal aortic aneurysm.	NEW	0.55	0.55	No.
77001	Fluoroscopic guidance for central venous access device placement, replacement (catheter only or complete), or removal (includes fluoroscopic guidance for vascular access and catheter manipulation, any necessary contrast injections through access site or catheter with related venography radiologic supervision and interpretation, and radiographic documentation of final catheter position).	0.38	0.38	0.38	No.
77002	Fluoroscopic guidance for needle placement (*e.g.*, biopsy, aspiration, injection, localization device).	0.54	0.54	0.38	No.
77003	Fluoroscopic guidance and localization of needle or catheter tip for spine or paraspinous diagnostic or therapeutic injection procedures (epidural or subarachnoid).	0.60	0.60	0.38	No.
770X1	Fluoroscopic guidance for central venous access device placement, replacement (catheter only or complete), or removal (includes fluoroscopic guidance for vascular access and catheter manipulation, any necessary contrast injections through access site or catheter with related venography radiologic supervision and interpretation, and radiographic documentation of final catheter position).	NEW	0.81	0.81	No.
770X2	Fluoroscopic guidance for needle placement (*e.g.*, biopsy, aspiration, injection, localization device).	NEW	1.00	1.00	No.
770X3	Fluoroscopic guidance and localization of needle or catheter tip for spine or paraspinous diagnostic or therapeutic injection procedures (epidural or subarachnoid).	NEW	0.76	0.76	No.
77332	Treatment devices, design and construction; simple (simple block, simple bolus).	0.54	0.54	0.45	No.
77333	Treatment devices, design and construction; intermediate (multiple blocks, stents, bite blocks, special bolus).	0.84	0.84	0.75	No.
77334	Treatment devices, design and construction; complex (irregular blocks, special shields, compensators, wedges, molds or casts).	1.24	1.24	1.15	No.
77470	Special treatment procedure (*e.g.*, total body irradiation, hemibody radiation, per oral or endocavitary irradiation).	2.09	2.03	2.03	No.

TABLE 23—PROPOSED CY 2017 WORK RVUS FOR NEW, REVISED AND POTENTIALLY MISVALUED CODES—Continued

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
77778	Interstitial radiation source application, complex, includes supervision, handling, loading of radiation source, when performed.	8.00		8.00	No.
77790	Supervision, handling, loading of radiation source	0.00		0.00	No.
78264	Gastric emptying imaging study (*e.g.,* solid, liquid, or both)	0.74		0.74	No.
78265	Gastric emptying imaging study (*e.g.,* solid, liquid, or both); with small bowel transit.	0.98		0.98	No.
78266	Gastric emptying imaging study (*e.g.,* solid, liquid, or both); with small bowel and colon transit, multiple days.	1.08		1.08	No.
88104	Cytopathology, fluids, washings or brushings, except cervical or vaginal; smears with interpretation.	0.56		0.56	No.
88106	Cytopathology, fluids, washings or brushings, except cervical or vaginal; simple filter method with interpretation.	0.37		0.37	No.
88108	Cytopathology, concentration technique, smears and interpretation (*e.g.,* Saccomanno technique).	0.44		0.44	No.
88112	Cytopathology, selective cellular enhancement technique with interpretation (*e.g.,* liquid based slide preparation method), except cervical or vaginal.	0.56		0.56	No.
88160	Cytopathology, smears, any other source; screening and interpretation.	0.50		0.50	No.
88161	Cytopathology, smears, any other source; preparation, screening and interpretation.	0.50		0.50	No.
88162	Cytopathology, smears, any other source; extended study involving over 5 slides and/or multiple stains.	0.76		0.76	No.
88184	Flow cytometry, cell surface, cytoplasmic, or nuclear marker, technical component only; first marker.	0.00	0.00	0.00	No.
88185	Flow cytometry, cell surface, cytoplasmic, or nuclear marker, technical component only; each additional marker.	0.00	0.00	0.00	No.
88187	Flow cytometry, interpretation; 2 to 8 markers	1.36	0.74	0.74	No.
88188	Flow cytometry, interpretation; 9 to 15 markers	1.69	1.40	1.20	No.
88189	Flow cytometry, interpretation; 16 or more markers	2.23	1.70	1.70	No.
88321	Consultation and report on referred slides prepared elsewhere.	1.63	1.63	1.63	No.
88323	Consultation and report on referred material requiring preparation of slides.	1.83	1.83	1.83	No.
88325	Consultation, comprehensive, with review of records and specimens, with report on referred material.	2.50	2.85	2.85	No.
88341	Immunohistochemistry or immunocytochemistry, per specimen; each additional single antibody stain procedure (List separately in addition to code for primary procedure).	0.53		0.56	No.
88364	In situ hybridization (*e.g.,* FISH), per specimen; each additional single probe stain procedure.	0.67		0.70	No.
88369	Morphometric analysis, in situ hybridization (quantitative or semi-quantitative), manual, per specimen; each additional single probe stain procedure.	0.67		0.67	No.
91110	Gastrointestinal tract imaging, intraluminal (*e.g.,* capsule endoscopy), esophagus through ileum, with interpretation and report.	3.64	2.49	2.49	No.
91111	Gastrointestinal tract imaging, intraluminal (*e.g.,* capsule endoscopy), esophagus with interpretation and report.	1.00	1.00	1.00	No.
91200	Liver elastography, mechanically induced shear wave (*e.g.,* vibration), without imaging, with interpretation and report.	0.27		0.27	No.
92132	Scanning computerized ophthalmic diagnostic imaging, anterior segment, with interpretation and report, unilateral or bilateral.	0.35	0.30	0.30	No.
92133	Scanning computerized ophthalmic diagnostic imaging, posterior segment, with interpretation and report, unilateral or bilateral; optic nerve.	0.50	0.40	0.40	No.
92134	Scanning computerized ophthalmic diagnostic imaging, posterior segment, with interpretation and report, unilateral or bilateral; retina.	0.50	0.45	0.45	No.
92235	Fluorescein angiography (includes multiframe imaging) with interpretation and report.	0.81	0.75	0.75	No.
92240	Indocyanine-green angiography (includes multiframe imaging) with interpretation and report.	1.10	0.80	0.80	No.
92250	Fundus photography with interpretation and report	0.44	0.40	0.40	No.
922X4	Fluorescein angiography and indocyanine-green angiography (includes multiframe imaging) performed at the same patient encounter with interpretation and report, unilateral or bilateral.	NEW	0.95	0.95	No.

TABLE 23—PROPOSED CY 2017 WORK RVUS FOR NEW, REVISED AND POTENTIALLY MISVALUED CODES—Continued

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
93050	Arterial pressure waveform analysis for assessment of central arterial pressures, includes obtaining waveform(s), digitization and application of nonlinear mathematical transformations to determine central arterial pressures and augmentation index, with interpretation and report, upper extremity artery, non-invasive.	0.17		0.17	No.
935X1	Percutaneous transcatheter closure of paravalvular leak; initial occlusion device, mitral valve.	NEW	21.70	18.23	No.
935X2	Percutaneous transcatheter closure of paravalvular leak; initial occlusion device, aortic valve.	NEW	17.97	14.50	No.
935X3	Percutaneous transcatheter closure of paravalvular leak; each additional occlusion device (list separately in addition to code for primary service).	NEW	8.00	6.81	No.
95144	Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy, single dose vial(s) (specify number of vials).	0.06	0.06	0.06	No.
95165	Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy; single or multiple antigens (specify number of doses).	0.06	0.06	0.06	No.
95812	Electroencephalogram (EEG) extended monitoring; 41–60 minutes.	1.08	1.08	1.08	No.
95813	Electroencephalogram (EEG) extended monitoring; greater than 1 hour.	1.73	1.63	1.63	No.
95957	Digital analysis of electroencephalogram (EEG) (*e.g.*, for epileptic spike analysis).	1.98	1.98	1.98	No.
95971	Electronic analysis of implanted neurostimulator pulse generator system (*e.g.*, rate, pulse amplitude, pulse duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); simple spinal cord, or peripheral (*i.e.*, peripheral nerve, sacral nerve, neuromuscular) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming.	0.78		0.78	No.
95972	Electronic analysis of implanted neurostimulator pulse generator system (*e.g.*, rate, pulse amplitude, pulse duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); complex spinal cord, or peripheral (*i.e*, peripheral nerve, sacral nerve, neuromuscular) (except cranial nerve) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming.	0.80		0.80	No.
961X0	Administration of patient-focused health risk assessment instrument (*e.g.*, health hazard appraisal) with scoring and documentation, per standardized instrument.	NEW	0.00	0.00	No.
961X1	Administration of caregiver-focused health risk assessment instrument (*e.g.*, depression inventory) for the benefit of the patient, with scoring and documentation, per standardized instrument.	NEW	0.00	0.00	No.
96931	Reflectance confocal microscopy (RCM) for cellular and sub-cellular imaging of skin; image acquisition and interpretation and report, first lesion.	0.00	0.80	0.75	No.
96932	Reflectance confocal microscopy (RCM) for cellular and sub-cellular imaging of skin; image acquisition only, first lesion.	0.00	0.00	0.00	No.
96933	Reflectance confocal microscopy (RCM) for cellular and sub-cellular imaging of skin; interpretation and report only, first lesion.	0.00	0.80	0.75	No.
96934	Reflectance confocal microscopy (RCM) for cellular and sub-cellular imaging of skin; image acquisition and interpretation and report, each additional lesion.	0.00	0.76	0.71	No.
96935	Reflectance confocal microscopy (RCM) for cellular and sub-cellular imaging of skin; image acquisition only, each additional lesion.	0.00	0.00	0.00	No.
96936	Reflectance confocal microscopy (RCM) for cellular and sub-cellular imaging of skin; interpretation and report only, each additional lesion.	0.00	0.76	0.71	No.
97X61	Physical therapy evaluation; low complexity	NEW	0.75	1.20	Yes.
97X62	Physical therapy evaluation; moderate complexity	NEW	1.18	1.20	No.
97X63	Physical therapy evaluation; high complexity	NEW	1.50	1.20	Yes.
97X64	Reevaluation of physical therapy established plan of care	NEW	0.75	0.60	No.

TABLE 23—PROPOSED CY 2017 WORK RVUS FOR NEW, REVISED AND POTENTIALLY MISVALUED CODES—Continued

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
97X65	Occupational therapy evaluation; low complexity	NEW	0.88	1.20	Yes.
97X66	Occupational therapy evaluation; moderate complexity	NEW	1.20	1.20	No.
97X67	Occupational therapy evaluation; high complexity	NEW	1.70	1.20	Yes.
97X68	Reevaluation of occupational therapy care/established plan of care.	NEW	0.80	0.60	No.
991X1	Moderate sedation services provided by the same physician or other qualified health care professional performing the diagnostic or therapeutic service that the sedation supports, requiring the presence of an independent trained observer to assist in the monitoring of the patient's level of consciousness and physiological status; initial 15 minutes of intra-service time, patient younger than 5 years of age.	NEW	0.50	0.50	No.
991X2	Moderate sedation services provided by the same physician or other qualified health care professional performing the diagnostic or therapeutic service that the sedation supports, requiring the presence of an independent trained observer to assist in the monitoring of the patient's level of consciousness and physiological status; initial 15 minutes of intra-service time, patient age 5 years or older.	NEW	0.25	0.25	No.
991X3	Moderate sedation services provided by a physician or other qualified health care professional other than the physician or other qualified health care professional performing the diagnostic or therapeutic service that the sedation supports; initial 15 minutes of intra-service time, patient younger than 5 years of age.	NEW	1.90	1.90	No.
991X4	Moderate sedation services provided by a physician or other qualified health care professional other than the physician or other qualified health care professional performing the diagnostic or therapeutic service that the sedation supports; initial 15 minutes of intra-service time, patient age 5 years or older.	NEW	1.84	1.65	No.
991X5	Moderate sedation services provided by the same physician or other qualified health care professional performing the diagnostic or therapeutic service that the sedation supports, requiring the presence of an independent trained observer to assist in the monitoring of the patient's level of consciousness and physiological status; each additional 15 minutes of intra-service time.	NEW	0.00	0.00	No.
991X6	Moderate sedation services provided by a physician or other qualified health care professional other than the physician or other qualified health care professional performing the diagnostic or therapeutic service that the sedation supports; each additional 15 minutes intra-service time.	NEW	1.25	1.25	No.
99354	Prolonged evaluation and management or psychotherapy service(s) (beyond the typical service time of the primary procedure) in the office or other outpatient setting requiring direct patient contact beyond the usual service; first hour.	1.77		2.33	No.
99358	Prolonged evaluation and management service before and/or after direct patient care; first hour.	2.10		2.10	No.
99359	Prolonged evaluation and management service before and/or after direct patient care; each additional 30 minutes.	1.00		1.00	No.
99487	Complex chronic care management services, with the following required elements: Multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline, establishment or substantial revision of a comprehensive care plan, moderate or high complexity medical decision making; 60 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month.	0.00		1.00	No.

Table 23—Proposed CY 2017 Work RVUs for New, Revised and Potentially Misvalued Codes—Continued

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
99489	Complex chronic care management services, with the following required elements: Multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline, establishment or substantial revision of a comprehensive care plan, moderate or high complexity medical decision making; 60 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month; each additional 30 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month.	0.00		0.50	No.
G0416	Surgical pathology, gross and microscopic examinations, for prostate needle biopsy, any method.	3.09	4.00	3.60	No.
GDDD1	Resource-intensive services for patients for whom the use of specialized mobility-assistive technology (such as adjustable height chairs or tables, patient lift, and adjustable padded leg supports) is medically necessary and used during the provision of an office/outpatient E/M visit (Add-on code, list separately in addition to primary procedure).	NEW		0.48	No.
GMMM1	Moderate sedation services provided by the same physician or other qualified health care professional performing a gastrointestinal endoscopic service (excluding biliary procedures) that the sedation supports, requiring the presence of an independent trained observer to assist in the monitoring of the patient's level of consciousness and physiological status; initial 15 minutes of intraservice time.	NEW		0.10	No.
GPPP1	Initial psychiatric collaborative care management, first 70 minutes in the first calendar month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional.	NEW		1.59	No.
GPPP2	Subsequent psychiatric collaborative care management, first 60 minutes in a subsequent month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional.	NEW		1.42	No.
GPPP3	Initial or subsequent psychiatric collaborative care management, each additional 30 minutes in a calendar month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional.	NEW		0.71	No.
GPPP6	Cognition and functional assessment using standardized instruments with development of recorded care plan for the patient with cognitive impairment, history obtained from patient and/or caregiver, in office or other outpatient setting or home or domiciliary or rest home.	NEW		3.30	No.
GPPP7	Comprehensive assessment of and care planning for patients requiring chronic care management services (billed separately from monthly care management services).	NEW		0.87	No.
GPPPX	Care management services for behavioral health conditions, at least 20 minutes of clinical staff time, directed by a physician or other qualified health care professional time, per calendar month.	NEW		0.61	No.
GTTT1	Telehealth consultation, critical care, physicians typically spend 60 minutes communicating with the patient via telehealth (initial).	NEW		4.00	No.
GTTT2	Telehealth consultation, critical care, physicians typically spend 50 minutes communicating with the patient via telehealth (subsequent).	NEW		3.86	No.

TABLE 24—CY 2016 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS ACCEPTED WITHOUT REFINEMENT

HCPCS code	Description
00740	Anesth upper gi visualize.
00810	Anesth low intestine scope.
10030	Guide cathet fluid drainage.
11730	Removal of nail plate.
19298	Place breast rad tube/caths.
20245	Bone biopsy excisional.
20550	Inj tendon sheath/ligament.
20552	Inj trigger point 1/2 muscl.
20553	Inject trigger points 3/>.
20982	Ablate bone tumor(s) perq.
20983	Ablate bone tumor(s) perq.
22510	Perq cervicothoracic inject.
22511	Perq lumbosacral injection.
22512	Vertebroplasty addl inject.
22513	Perq vertebral augmentation.
22514	Perq vertebral augmentation.
22515	Perq vertebral augmentation.
22526	Idet single level.
22527	Idet 1 or more levels.
228X1	Insj stablj dev w/dcmprn.
228X4	Insj stablj dev w/o dcmprn.
28289	Repair hallux rigidus.
28292	Correction of bunion.
28296	Correction of bunion.
28297	Correction of bunion.
28298	Correction of bunion.
28299	Correction of bunion.
282X1	Corrj halux rigdus w/implt.
31615	Visualization of windpipe.
31622	Dx bronchoscope/wash.
31623	Dx bronchoscope/brush.
31624	Dx bronchoscope/lavage.
31625	Bronchoscopy w/biopsy(s).
31626	Bronchoscopy w/markers.
31627	Navigational bronchoscopy.
31628	Bronchoscopy/lung bx each.
31629	Bronchoscopy/needle bx each.
31632	Bronchoscopy/lung bx addl.
31633	Bronchoscopy/needle bx addl.
31634	Bronch w/balloon occlusion.
31635	Bronchoscopy w/fb removal.
31645	Bronchoscopy clear airways.
31646	Bronchoscopy reclear airway.
31652	Bronch ebus samplng 1/2 node.
31653	Bronch ebus samplng 3/> node.
31654	Bronch ebus ivntj perph les.
32405	Percut bx lung/mediastinum.
32550	Insert pleural cath.
32553	Ins mark thor for rt perq.
333X3	Perq clsr tcat l atr apndge.
334X1	Valvuloplasty aortic valve.
334X2	Valvuloplasty aortic valve.
35471	Repair arterial blockage.
35472	Repair arterial blockage.
35475	Repair arterial blockage.
35476	Repair venous blockage.
36010	Place catheter in vein.
36140	Establish access to artery.
36147	Access av dial grft for eval.
36148	Access av dial grft for proc.
36200	Place catheter in aorta.
36221	Place cath thoracic aorta.
36222	Place cath carotid/inom art.
36223	Place cath carotid/inom art.
36224	Place cath carotid art.
36225	Place cath subclavian art.
36226	Place cath vertebral art.
36227	Place cath xtrnl carotid.
36228	Place cath intracranial art.
36245	Ins cath abd/l-ext art 1st.
36246	Ins cath abd/l-ext art 2nd.
36247	Ins cath abd/l-ext art 3rd.
36248	Ins cath abd/l-ext art addl.
36251	Ins cath ren art 1st unilat.
36252	Ins cath ren art 1st bilat.
36253	Ins cath ren art 2nd+ unilat.
36254	Ins cath ren art 2nd+ bilat.
36481	Insertion of catheter vein.
36555	Insert non-tunnel cv cath.
36557	Insert tunneled cv cath.
36558	Insert tunneled cv cath.
36560	Insert tunneled cv cath.
36561	Insert tunneled cv cath.
36563	Insert tunneled cv cath.
36565	Insert tunneled cv cath.
36566	Insert tunneled cv cath.
36568	Insert picc cath.
36570	Insert picvad cath.
36571	Insert picvad cath.
36576	Repair tunneled cv cath.
36578	Replace tunneled cv cath.
36581	Replace tunneled cv cath.
36582	Replace tunneled cv cath.
36583	Replace tunneled cv cath.
36585	Replace picvad cath.
36590	Removal tunneled cv cath.
36870	Percut thrombect av fistula.
369X7	Balo angiop ctr dialysis seg.
369X8	Stent plmt ctr dialysis seg.
369X9	Dialysis circuit embolj.
37183	Remove hepatic shunt (tips).
37184	Prim art m-thrmbc 1st vsl.
37185	Prim art m-thrmbc sbsq vsl.
37186	Sec art thrombectomy add-on.
37187	Venous mech thrombectomy.
37188	Venous m-thrombectomy add-on.
37191	Ins endovas vena cava filtr.
37192	Redo endovas vena cava filtr.
37193	Rem endovas vena cava filter.
37197	Remove intrvas foreign body.
37220	Iliac revasc.
37221	Iliac revasc w/stent.
37222	Iliac revasc add-on.
37223	Iliac revasc w/stent add-on.
37224	Fem/popl revas w/tla.
37225	Fem/popl revas w/ather.
37226	Fem/popl revasc w/stent.
37227	Fem/popl revasc stnt & ather.
37228	Tib/per revasc w/tla.
37229	Tib/per revasc w/ather.
37230	Tib/per revasc w/stent.
37231	Tib/per revasc stent & ather.
37232	Tib/per revasc add-on.
37233	Tibper revasc w/ather add-on.
37234	Revsc opn/prq tib/pero stent.
37235	Tib/per revasc stnt & ather.
37236	Open/perq place stent 1st.
37237	Open/perq place stent ea add.
37238	Open/perq place stent same.
37239	Open/perq place stent ea add.
37241	Vasc embolize/occlude venous.
37242	Vasc embolize/occlude artery.
37243	Vasc embolize/occlude organ.
37244	Vasc embolize/occlude bleed.
37252	Intrvasc us noncoronary 1st.
37253	Intrvasc us noncoronary addl.
372X2	Trluml balo angiop addl art.
372X4	Trluml balo angiop addl vein.
43200	Esophagoscopy flexible brush.
43201	Esoph scope w/submucous inj.
43202	Esophagoscopy flex biopsy.
43206	Esoph optical endomicroscopy.
43213	Esophagoscopy retro balloon.
43215	Esophagoscopy flex remove fb.
43216	Esophagoscopy lesion removal.
43217	Esophagoscopy snare les remv.
43220	Esophagoscopy balloon <30 mm.
43226	Esoph endoscopy dilation.
43227	Esophagoscopy control bleed.
43229	Esophagoscopy lesion ablate.
43231	Esophagoscop ultrasound exam.
43232	Esophagoscopy w/us needle bx.
43235	Egd diagnostic brush wash.
43236	Uppr gi scope w/submuc inj.
43239	Egd biopsy single/multiple.
43245	Egd dilate stricture.
43247	Egd remove foreign body.
43248	Egd guide wire insertion.
43249	Esoph egd dilation <30 mm.
43250	Egd cautery tumor polyp.
43251	Egd remove lesion snare.
43252	Egd optical endomicroscopy.
43255	Egd control bleeding any.
43270	Egd lesion ablation.
432X1	Laps esophgl sphnctr agmnt.
432X2	Rmvl esophgl sphnctr dev.
43450	Dilate esophagus 1/mult pass.
43453	Dilate esophagus.
44380	Small bowel endoscopy br/wa.
44381	Small bowel endoscopy br/wa.
44382	Small bowel endoscopy.
44385	Endoscopy of bowel pouch.
44386	Endoscopy bowel pouch/biop.
44388	Colonoscopy thru stoma spx.
44389	Colonoscopy with biopsy.
44390	Colonoscopy for foreign body.
44391	Colonoscopy for bleeding.
44392	Colonoscopy & polypectomy.
44394	Colonoscopy w/snare.
44401	Colonoscopy with ablation.
44404	Colonoscopy w/injection.
44405	Colonoscopy w/dilation.
45303	Proctosigmoidoscopy dilate.
45305	Proctosigmoidoscopy w/bx.

Table 24—CY 2016 Proposed Codes With Direct PE Input Recommendations Accepted Without Refinement—Continued

HCPCS code	Description
45307	Proctosigmoidoscopy fb.
45308	Proctosigmoidoscopy removal.
45309	Proctosigmoidoscopy removal.
45315	Proctosigmoidoscopy removal.
45317	Proctosigmoidoscopy bleed.
45320	Proctosigmoidoscopy ablate.
45332	Sigmoidoscopy w/fb removal.
45333	Sigmoidoscopy & polypectomy.
45334	Sigmoidoscopy for bleeding.
45335	Sigmoidoscopy w/submuc inj.
45338	Sigmoidoscopy w/tumr remove.
45340	Sig w/tndsc balloon dilation.
45346	Sigmoidoscopy w/ablation.
45350	Sgmdsc w/band ligation.
45378	Diagnostic colonoscopy.
45379	Colonoscopy w/fb removal.
45380	Colonoscopy and biopsy.
45381	Colonoscopy submucous njx.
45382	Colonoscopy w/control bleed.
45384	Colonoscopy w/lesion removal.
45385	Colonoscopy w/lesion removal.
45386	Colonoscopy w/balloon dilat.
45388	Colonoscopy w/ablation.
45398	Colonoscopy w/band ligation.
47000	Needle biopsy of liver.
47382	Percut ablate liver rf.
47383	Perq abltj lvr cryoablation.
49405	Image cath fluid colxn visc.
49406	Image cath fluid peri/retro.
49407	Image cath fluid trns/vgnl.
49411	Ins mark abd/pel for rt perq.
49418	Insert tun ip cath perc.
49440	Place gastrostomy tube perc.
49441	Place duod/jej tube perc.
49442	Place cecostomy tube perc.
49446	Change g-tube to g-j perc.
50200	Renal biopsy perq.
50382	Change ureter stent percut.
50384	Remove ureter stent percut.
50385	Change stent via transureth.
50386	Remove stent via transureth.
50387	Change nephroureteral cath.
50430	Njx px nfrosgrm &/urtrgrm.
50432	Plmt nephrostomy catheter.
50433	Plmt nephroureteral catheter.
50434	Convert nephrostomy catheter.
50592	Perc rf ablate renal tumor.
50593	Perc cryo ablate renal tum.
50693	Plmt ureteral stent prq.
50694	Plmt ureteral stent prq.
50695	Plmt ureteral stent prq.
51702	Insert temp bladder cath.
51703	Insert bladder cath complex.
51720	Treatment of bladder lesion.
51784	Anal/urinary muscle study.
55700	Biopsy of prostate.
57155	Insert uteri tandem/ovoids.
58558	Hysteroscopy biopsy.
58559	Hysteroscopy lysis.
58560	Hysteroscopy resect septum.
58561	Hysteroscopy remove myoma.
58563	Hysteroscopy ablation.
585X1	Laps abltj uterine fibroids.
630X1	Ndsc dcmprn 1 ntrspc lumbar.
66720	Destruction ciliary body.
67101	Repair detached retina.
67105	Repair detached retina.
69300	Revise external ear.
767X1	Us abdl aorta screen aaa.
77332	Radiation treatment aid(s).
77333	Radiation treatment aid(s).
77334	Radiation treatment aid(s).
77470	Special radiation treatment.
77600	Hyperthermia treatment.
77605	Hyperthermia treatment.
77610	Hyperthermia treatment.
77615	Hyperthermia treatment.
91110	Gi tract capsule endoscopy.
91111	Esophageal capsule endoscopy.
92132	Cmptr ophth dx img ant segmt.
92133	Cmptr ophth img optic nerve.
92134	Cptr ophth dx img post segmt.
92235	Eye exam with photos.
92240	Icg angiography.
92250	Eye exam with photos.
922X4	Fluorescein icg angiography.
92960	Cardioversion electric ext.
93312	Echo transesophageal.
93314	Echo transesophageal.
93451	Right heart cath.
93452	Left hrt cath w/ventrclgrphy.
93453	R&l hrt cath w/ventriclgrphy.
93454	Coronary artery angio s&i.
93455	Coronary art/grft angio s&i.
93456	R hrt coronary artery angio.
93457	R hrt art/grft angio.
93458	L hrt artery/ventricle angio.
93459	L hrt art/grft angio.
93460	R&l hrt art/ventricle angio.
93461	R&l hrt art/ventricle angio.
93464	Exercise w/hemodynamic meas.
93505	Biopsy of heart lining.
93566	Inject r ventr/atrial angio.
93567	Inject suprvlv aortography.
93568	Inject pulm art hrt cath.
935X1	Perq transcath cls mitral.
935X2	Perq transcath cls aortic.
93642	Electrophysiology evaluation.
93644	Electrophysiology evaluation.
95144	Antigen therapy services.
95165	Antigen therapy services.
95957	Eeg digital analysis.
961X0	Pt-focused hlth risk assmt.
961X1	Caregiver health risk assmt.
96440	Chemotherapy intracavitary.
96931	Rcm celulr subcelulr img skn.
96932	Rcm celulr subcelulr img skn.
97X64	Pt re-eval est plan care.
97X68	Ot re-eval est plan care.
991X1	Mod sed same phys/qhp <5 yrs.
991X2	Mod sed same phys/qhp 5/>yrs.
991X5	Mod sed oth phys/qhp 5/>yrs.
G0341	Percutaneous islet celltrans.
GMMM1	

TABLE 25: CY 2016 Proposed Codes With Direct PE Input Recommendations Accepted With Refinement

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
11732	Remove nail plate add-on	EF015	mayo stand	NF		0	8	See preamble text	$0.01
11732	Remove nail plate add-on	EF031	table, power	NF		7	8	Refined equipment time to conform to changes in clinical labor time	$0.02
11732	Remove nail plate add-on	EQ137	instrument pack, basic ($500-$1499)	NF		0	8	See preamble text	$0.02
11732	Remove nail plate add-on	EQ168	light, exam	NF		7	8	Refined equipment time to conform to changes in clinical labor time	$0.00
11732	Remove nail plate add-on	L037D	RN/LPN/MTA	NF	Assist physician in performing procedure	7	8	See preamble text	$0.37
11732	Remove nail plate add-on	SC031	needle, 30g	NF		1	0	Add-on code. Additional supplies not typical; see preamble text	-$0.34
11732	Remove nail plate add-on	SC051	syringe 10-12ml	NF		1	0	Add-on code. Additional supplies not typical; see preamble text	-$0.18
11732	Remove nail plate add-on	SG067	penrose drain (0.25in x 4in)	NF		1	0	Add-on code. Additional supplies not typical; see preamble text	-$0.50

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
11732	Remove nail plate add-on	SH047	lidocaine 1%-2% inj (Xylocaine)	NF		10	0	Add-on code. Additional supplies not typical; see preamble text	-$0.35
11732	Remove nail plate add-on	SH064	silver sulfadiazene cream (Silvadene)	NF		0.5	0	Add-on code. Additional supplies not typical; see preamble text	-$0.08
11732	Remove nail plate add-on	SJ053	swab-pad, alcohol	NF		2	1	Add-on code. Additional supplies not typical; see preamble text	-$0.01
271X1	Clsd tx pelvic ring fx	L037D	RN/LPN/MTA	F	99213 36 minutes	1	0	See preamble text	-$13.32
271X1	Clsd tx pelvic ring fx	L037D	RN/LPN/MTA	F	99212 27 minutes	2	0	See preamble text	-$19.98
271X2	Clsd tx pelvic ring fx	L037D	RN/LPN/MTA	F	99212 27 minutes	1	0	See preamble text	-$9.99
271X2	Clsd tx pelvic ring fx	L037D	RN/LPN/MTA	F	99213 36 minutes	2	0	See preamble text	-$26.64
31575	Diagnostic laryngoscopy	EF008	chair with headrest, exam, reclining	NF		23	20	Refined equipment time to conform to changes in clinical labor time	-$0.03
31575	Diagnostic laryngoscopy	EQ167	light source, xenon	NF		0	17	Refined equipment time to conform to established policies for scope accessories	$0.47
31575	Diagnostic laryngoscopy	EQ170	light, fiberoptic headlight w-source	NF		23	20	Refined equipment time to conform to changes in clinical labor time	-$0.02

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
31575	Diagnostic laryngoscopy	EQ234	suction and pressure cabinet, ENT (SMR)	NF		23	20	Refined equipment time to conform to changes in clinical labor time	-$0.03
31575	Diagnostic laryngoscopy	ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart)	NF		0	17	Refined equipment time to conform to established policies for scope accessories	$1.01
31575	Diagnostic laryngoscopy	ES060	Video-flexible laryngoscope system	NF		44	0	See preamble text	-$14.00
31575	Diagnostic laryngoscopy	ES063	rhinolaryngoscope, flexible, video, non-channeled	NF		0	47	Refined equipment time to conform to established policies for scopes	$2.18
31575	Diagnostic laryngoscopy	L037D	RN/LPN/MTA	NF	Clean room/equipment by physician staff	3	0	Clinical labor task redundant with clinical labor task "Assist physician in performing the procedure" (L041B)	-$1.11

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
31576	Laryngoscopy with biopsy	EQ167	light source, xenon	NF		0	28	Refined equipment time to conform to established policies for scope accessories	$0.78
31576	Laryngoscopy with biopsy	ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart)	NF		0	28	Refined equipment time to conform to established policies for scope accessories	$1.67
31576	Laryngoscopy with biopsy	ES061	Video-flexible channeled laryngoscope system	NF		55	0	See preamble text	-$21.23
31576	Laryngoscopy with biopsy	ES064	rhinolaryngoscope, flexible, video, channeled	NF		0	55	Refined equipment time to conform to established policies for scopes	$2.87
31577	Remove foreign body larynx	EF008	chair with headrest, exam, reclining	NF		99	95	Refined equipment time to conform to changes in clinical labor time	-$0.04
31577	Remove foreign body larynx	EF015	mayo stand	NF		99	95	Refined equipment time to conform to changes in clinical labor time	$0.00

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
31577	Remove foreign body larynx	EQ137	instrument pack, basic ($500-$1499)	NF		40	39	Refined equipment time to conform to changes in clinical labor time	$0.00
31577	Remove foreign body larynx	EQ167	light source, xenon	NF		0	29	Refined equipment time to conform to established policies for scope accessories	$0.80
31577	Remove foreign body larynx	EQ170	light, fiberoptic headlight w-source	NF		99	95	Refined equipment time to conform to changes in clinical labor time	-$0.03
31577	Remove foreign body larynx	EQ234	suction and pressure cabinet, ENT (SMR)	NF		99	95	Refined equipment time to conform to changes in clinical labor time	-$0.04
31577	Remove foreign body larynx	ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart)	NF		0	29	Refined equipment time to conform to established policies for scope accessories	$1.73
31577	Remove foreign body larynx	ES061	Video-flexible channeled laryngoscope system	NF		54	0	See preamble text	-$20.84

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
31577	Remove foreign body larynx	ES064	rhinolaryngoscope, flexible, video, channeled	NF		0	59	Refined equipment time to conform to established policies for scopes	$3.08
31577	Remove foreign body larynx	L037D	RN/LPN/MTA	NF	Clean room/equipment by physician staff	3	0	Clinical labor task redundant with clinical labor task "Assist physician in performing the procedure" (L041B)	-$1.11
31577	Remove foreign body larynx	L037D	RN/LPN/MTA	NF	Obtain vital signs	3	2	Clinical labor task redundant with clinical labor task "Assist physician in performing the procedure" (L041B)	-$0.37
31578	Removal of larynx lesion	EQ167	light source, xenon	NF		0	33	Refined equipment time to conform to established policies for scope accessories	$0.92
31578	Removal of larynx lesion	ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart)	NF		0	33	Refined equipment time to conform to established policies for scope accessories	$1.97

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
31578	Removal of larynx lesion	ES061	Video-flexible channeled laryngoscope system	NF		54	0	See preamble text	-$20.84
31578	Removal of larynx lesion	ES064	rhinolaryngoscope, flexible, video, channeled	NF		0	60	Refined equipment time to conform to established policies for scopes	$3.13
31579	Diagnostic laryngoscopy	EF008	chair with headrest, exam, reclining	NF		31	27	Refined equipment time to conform to changes in clinical labor time	-$0.04
31579	Diagnostic laryngoscopy	EF015	mayo stand	NF		31	27	Refined equipment time to conform to changes in clinical labor time	$0.00
31579	Diagnostic laryngoscopy	EQ167	light source, xenon	NF		0	24	Refined equipment time to conform to established policies for scope accessories	$0.67
31579	Diagnostic laryngoscopy	EQ170	light, fiberoptic headlight w-source	NF		31	27	Refined equipment time to conform to changes in clinical labor time	-$0.03

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
31579	Diagnostic laryngoscopy	EQ234	suction and pressure cabinet, ENT (SMR)	NF		31	27	Refined equipment time to conform to changes in clinical labor time	-$0.04
31579	Diagnostic laryngoscopy	ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart)	NF		0	24	Refined equipment time to conform to established policies for scope accessories	$1.43
31579	Diagnostic laryngoscopy	ES063	rhinolaryngoscope, flexible, video, non-channeled	NF		0	54	Refined equipment time to conform to established policies for scopes	$2.50
31579	Diagnostic laryngoscopy	ES065	stroboscopy system	NF		49	44	Refined equipment time to conform to established policies for scope accessories	-$0.38
31579	Diagnostic laryngoscopy	L037D	RN/LPN/MTA	NF	Obtain vital signs	3	2	Clinical labor task redundant with clinical labor task "Assist physician in performing the procedure" (L041B)	-$0.37

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31579	Diagnostic laryngoscopy	L037D	RN/LPN/MTA	NF	Clean room/equipment by physician staff	3	0	Clinical labor task redundant with clinical labor task "Assist physician in performing the procedure" (L041B)	-$1.11
31580	Revision of larynx	EQ137	instrument pack, basic ($500-$1499)	F		138	129	Refined equipment time to conform to established policies for surgical instrument packs	-$0.02
31580	Revision of larynx	EQ167	light source, xenon	F		0	108	Equipment item replaces another item; see preamble text EQ170	$3.00
31580	Revision of larynx	EQ170	light, fiberoptic headlight w-source	F		108	0	Equipment item replaced by another item; see preamble text EQ167	-$0.85
31580	Revision of larynx	ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart)	F		0	108	Refined equipment time to conform to established policies for scope accessories	$6.44
31580	Revision of larynx	ES060	Video-flexible laryngoscope system	F		198	0	See preamble text	-$62.98

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31580	Revision of larynx	ES063	rhinolaryngoscope, flexible, video, non-channeled	F		0	189	Refined equipment time to conform to established policies for scopes	$8.76
31584	Treat larynx fracture	EQ137	instrument pack, basic ($500-$1499)	F		138	129	Refined equipment time to conform to established policies for surgical instrument packs	-$0.02
31584	Treat larynx fracture	EQ167	light source, xenon	F		0	108	Equipment item replaces another item; see preamble text EQ170	$3.00
31584	Treat larynx fracture	EQ170	light, fiberoptic headlight w-source	F		108	0	Equipment item replaced by another item; see preamble text EQ167	-$0.85
31584	Treat larynx fracture	ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart)	F		0	108	Refined equipment time to conform to established policies for scope accessories	$6.44
31584	Treat larynx fracture	ES060	Video-flexible laryngoscope system	F		198	0	See preamble text	-$62.98

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
31584	Treat larynx fracture	ES063	rhinolaryngoscope, flexible, video, non-channeled	F		0	189	Refined equipment time to conform to established policies for scopes	$8.76
31587	Revision of larynx	EQ137	instrument pack, basic ($500-$1499)	F		138	129	Refined equipment time to conform to established policies for surgical instrument packs	-$0.02
31587	Revision of larynx	EQ167	light source, xenon	F		0	108	Equipment item replaces another item; see preamble text EQ170	$3.00
31587	Revision of larynx	EQ170	light, fiberoptic headlight w-source	F		108	0	Equipment item replaced by another item; see preamble text EQ167	-$0.85
31587	Revision of larynx	ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart)	F		0	108	Refined equipment time to conform to established policies for scope accessories	$6.44
31587	Revision of larynx	ES060	Video-flexible laryngoscope system	F		198	0	See preamble text	-$62.98

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
31587	Revision of larynx	ES063	rhinolaryngoscope, flexible, video, non-channeled	F		0	189	Refined equipment time to conform to established policies for scopes	$8.76
317X1	Largsc w/laser dstrj les	EQ167	light source, xenon	NF		0	38	Refined equipment time to conform to established policies for scope accessories	$1.05
317X1	Largsc w/laser dstrj les	ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart)	NF		0	38	Refined equipment time to conform to established policies for scope accessories	$2.27
317X1	Largsc w/laser dstrj les	ES061	Video-flexible channeled laryngoscope system	NF		59	0	See preamble text	-$22.77
317X1	Largsc w/laser dstrj les	ES064	rhinolaryngoscope, flexible, video, channeled	NF		0	65	Refined equipment time to conform to established policies for scopes	$3.39
317X1	Largsc w/laser dstrj les	SF029	laser tip, bare (single use)	NF		0	1	Supply item replaces another item; see preamble SF030	$150.00

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317X1	Largsc w/laser dstrj les	SF030	laser tip, diffuser fiber	NF		1	0	Supply item replaced by another item; see preamble SF029	-$197.50
317X2	Largsc w/ther injection	EQ167	light source, xenon	NF		0	33	Refined equipment time to conform to established policies for scope accessories	$0.92
317X2	Largsc w/ther injection	ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart)	NF		0	33	Refined equipment time to conform to established policies for scope accessories	$1.97
317X2	Largsc w/ther injection	ES061	Video-flexible channeled laryngoscope system	NF		54	0	See preamble text	-$20.84
317X2	Largsc w/ther injection	ES064	rhinolaryngoscope, flexible, video, channeled	NF		0	60	Refined equipment time to conform to established policies for scopes	$3.13
317X3	Largsc w/njx augmentation	EQ167	light source, xenon	NF		0	33	Refined equipment time to conform to established policies for scope accessories	$0.92

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317X3	Largsc w/njx augmentation	ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart)	NF		0	33	Refined equipment time to conform to established policies for scope accessories	$1.97
317X3	Largsc w/njx augmentation	ES060	Video-flexible laryngoscope system	NF		60	0	See preamble text	-$19.09
317X3	Largsc w/njx augmentation	ES063	rhinolaryngoscope, flexible, video, non-channeled	NF		0	60	Refined equipment time to conform to established policies for scopes	$2.78
315X1	Laryngoplasty laryngeal sten	EQ137	instrument pack, basic ($500-$1499)	F		138	129	Refined equipment time to conform to established policies for surgical instrument packs	-$0.02
315X1	Laryngoplasty laryngeal sten	EQ167	light source, xenon	F		0	108	Equipment item replaces another item; see preamble text EQ170	$3.00
315X1	Laryngoplasty laryngeal sten	EQ170	light, fiberoptic headlight w-source	F		108	0	Equipment item replaced by another item; see preamble text EQ167	-$0.85

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315X1	Laryngoplasty laryngeal sten	ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart)	F		0	108	Refined equipment time to conform to established policies for scope accessories	$6.44
315X1	Laryngoplasty laryngeal sten	ES060	Video-flexible laryngoscope system	F		198	0	See preamble text	-$62.98
315X1	Laryngoplasty laryngeal sten	ES063	rhinolaryngoscope, flexible, video, non-channeled	F		0	189	Refined equipment time to conform to established policies for scopes	$8.76
315X2	Laryngoplasty laryngeal sten	EQ137	instrument pack, basic ($500-$1499)	F		138	129	Refined equipment time to conform to established policies for surgical instrument packs	-$0.02
315X2	Laryngoplasty laryngeal sten	EQ167	light source, xenon	F		0	108	Equipment item replaces another item; see preamble text EQ170	$3.00
315X2	Laryngoplasty laryngeal sten	EQ170	light, fiberoptic headlight w-source	F		108	0	Equipment item replaced by another item; see preamble text EQ167	-$0.85
315X2	Laryngoplasty laryngeal sten	ES031	video system, endoscopy (processor, digital capture, monitor,	F		0	108	Refined equipment time to conform to established policies for scope accessories	$6.44

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
			printer, cart)						
315X2	Laryngoplasty laryngeal sten	ES060	Video-flexible laryngoscope system	F		198	0	See preamble text	-$62.98
315X2	Laryngoplasty laryngeal sten	ES063	rhinolaryngoscope, flexible, video, non-channeled	F		0	189	Refined equipment time to conform to established policies for scopes	$8.76
315X3	Laryngoplasty laryngeal sten	EQ137	instrument pack, basic ($500-$1499)	F		138	129	Refined equipment time to conform to established policies for surgical instrument packs	-$0.02
315X3	Laryngoplasty laryngeal sten	EQ167	light source, xenon	F		0	108	Equipment item replaces another item; see preamble text EQ170	$3.00
315X3	Laryngoplasty laryngeal sten	EQ170	light, fiberoptic headlight w-source	F		108	0	Equipment item replaced by another item; see preamble text EQ167	-$0.85

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
315X3	Laryngoplasty laryngeal sten	ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart)	F		0	108	Refined equipment time to conform to established policies for scope accessories	$6.44
315X3	Laryngoplasty laryngeal sten	ES060	Video-flexible laryngoscope system	F		198	0	See preamble text	-$62.98
315X3	Laryngoplasty laryngeal sten	ES063	rhinolaryngoscope, flexible, video, non-channeled	F		0	189	Refined equipment time to conform to established policies for scopes	$8.76
315X4	Laryngoplasty laryngeal sten	EQ137	instrument pack, basic ($500-$1499)	F		138	129	Refined equipment time to conform to established policies for surgical instrument packs	-$0.02
315X4	Laryngoplasty laryngeal sten	EQ167	light source, xenon	F		0	108	Equipment item replaces another item; see preamble text EQ170	$3.00
315X4	Laryngoplasty laryngeal sten	EQ170	light, fiberoptic headlight w-source	F		108	0	Equipment item replaced by another item; see preamble text EQ167	-$0.85
315X4	Laryngoplasty laryngeal sten	ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart)	F		0	108	Refined equipment time to conform to established policies for scope accessories	$6.44

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
315X4	Laryngoplasty laryngeal sten	ES060	Video-flexible laryngoscope system	F		198	0	See preamble text	-$62.98
315X4	Laryngoplasty laryngeal sten	ES063	rhinolaryngoscope, flexible, video, non-channeled	F		0	189	Refined equipment time to conform to established policies for scopes	$8.76
315X5	Laryngoplasty medialization	EQ137	instrument pack, basic ($500-$1499)	F		138	129	Refined equipment time to conform to established policies for surgical instrument packs	-$0.02
315X5	Laryngoplasty medialization	EQ167	light source, xenon	F		0	108	Equipment item replaces another item; see preamble text EQ170	$3.00
315X5	Laryngoplasty medialization	EQ170	light, fiberoptic headlight w-source	F		108	0	Equipment item replaced by another item; see preamble text EQ167	-$0.85
315X5	Laryngoplasty medialization	ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart)	F		0	108	Refined equipment time to conform to established policies for scope accessories	$6.44
315X5	Laryngoplasty medialization	ES060	Video-flexible laryngoscope system	F		198	0	See preamble text	-$62.98
315X5	Laryngoplasty medialization	ES063	rhinolaryngoscope, flexible, video, non-channeled	F		0	189	Refined equipment time to conform to established policies for scopes	$8.76
315X6	Cricotracheal resection	EQ137	instrument pack, basic ($500-$1499)	F		138	129	Refined equipment time to conform to established policies for surgical instrument packs	-$0.02

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315X6	Cricotracheal resection	EQ167	light source, xenon	F		0	108	Equipment item replaces another item; see preamble text EQ170	$3.00
315X6	Cricotracheal resection	EQ170	light, fiberoptic headlight w-source	F		108	0	Equipment item replaced by another item; see preamble text EQ167	-$0.85
315X6	Cricotracheal resection	ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart)	F		0	108	Refined equipment time to conform to established policies for scope accessories	$6.44
315X6	Cricotracheal resection	ES060	Video-flexible laryngoscope system	F		198	0	See preamble text	-$62.98
315X6	Cricotracheal resection	ES063	rhinolaryngoscope, flexible, video, non-channeled	F		0	189	Refined equipment time to conform to established policies for scopes	$8.76
364X2	Endovenous mchnchem add-on	EF014	light, surgical	NF		0	30	Equipment item replaces another item; see preamble text EL015	$0.30
364X2	Endovenous mchnchem add-on	EF031	table, power	NF		0	30	Equipment item replaces another item; see preamble text EL015	$0.49

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364X2	Endovenous mchnchem add-on	EL015	room, ultrasound, general	NF		30	0	Equipment item replaced by another item; see preamble text EQ250	-$42.05
364X2	Endovenous mchnchem add-on	EQ250	ultrasound unit, portable	NF		0	30	Equipment item replaces another item; see preamble text EL015	$3.49
364X2	Endovenous mchnchem add-on	SH108	Sotradecol Sclerosing Agent	NF		2	1	Refined supply quantity to what is typical for the procedure	-$110.20
369X1	Intro cath dialysis circuit	ED050	PACS Workstation Proxy	NF		54	52	Refined equipment time to conform to changes in clinical labor time	-$0.04
369X1	Intro cath dialysis circuit	EL011	room, angiography	NF		37	35	Refined equipment time to conform to changes in clinical labor time	-$10.51
369X1	Intro cath dialysis circuit	L037D	RN/LPN/MTA	NF	Prepare and position pt/ monitor pt/ set up IV	5	3	See preamble text	-$0.74
369X2	Intro cath dialysis circuit	ED050	PACS Workstation Proxy	NF		69	67	Refined equipment time to conform to changes in clinical labor time	-$0.04
369X2	Intro cath dialysis circuit	EL011	room, angiography	NF		52	50	Refined equipment time to conform to changes in clinical labor time	-$10.51
369X2	Intro cath dialysis circuit	L037D	RN/LPN/MTA	NF	Prepare and position pt/	5	3	See preamble text	-$0.74

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					monitor pt/ set up IV				
369X3	Intro cath dialysis circuit	ED050	PACS Workstation Proxy	NF		79	77	Refined equipment time to conform to changes in clinical labor time	-$0.04
369X3	Intro cath dialysis circuit	EL011	room, angiography	NF		62	60	Refined equipment time to conform to changes in clinical labor time	-$10.51
369X3	Intro cath dialysis circuit	L037D	RN/LPN/MTA	NF	Prepare and position pt/ monitor pt/ set up IV	5	3	See preamble text	-$0.74
369X3	Intro cath dialysis circuit	SA103	stent, vascular, deployment system, Cordis SMART	NF		0	1	Supply item replaces another item; see preamble SD254	$1,645.00
369X3	Intro cath dialysis circuit	SD254	covered stent (VIABAHN, Gore)	NF		1	0	Supply item replaced by another item; see preamble SA103	-$3,768.00
369X4	Thrmbc/nfs dialysis circuit	ED050	PACS Workstation Proxy	NF		89	87	Refined equipment time to conform to changes in clinical labor time	-$0.04
369X4	Thrmbc/nfs dialysis circuit	EL011	room, angiography	NF		72	70	Refined equipment time to conform to changes in clinical labor time	-$10.51

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369X4	Thrmbc/nfs dialysis circuit	L037D	RN/LPN/MTA	F	Schedule space and equipment in facility	6	3	Refined clinical labor time to conform with identical labor activity in other codes in the family	-$1.11
369X4	Thrmbc/nfs dialysis circuit	L037D	RN/LPN/MTA	F	Complete preservice diagnostic and referral forms	3	0	Refined clinical labor time to conform with identical labor activity in other codes in the family	-$1.11
369X4	Thrmbc/nfs dialysis circuit	L037D	RN/LPN/MTA	F	Follow-up phone calls and prescriptions	6	0	Refined clinical labor time to conform with identical labor activity in other codes in the family	-$2.22
369X4	Thrmbc/nfs dialysis circuit	L037D	RN/LPN/MTA	NF	Prepare and position pt/ monitor pt/ set up IV	5	3	See preamble text	-$0.74
369X4	Thrmbc/nfs dialysis circuit	L037D	RN/LPN/MTA	NF	Follow-up phone calls and prescriptions	6	3	Refined clinical labor time to conform with identical labor activity in other codes in the family	-$1.11
369X4	Thrmbc/nfs dialysis circuit	L037D	RN/LPN/MTA	F	Coordinate pre-surgery services	6	3	Refined clinical labor time to conform with identical labor activity in other codes in the family	-$1.11

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369X4	Thrmbc/nfs dialysis circuit	L037D	RN/LPN/MTA	NF	Coordinate pre-surgery services	6	3	Refined clinical labor time to conform with identical labor activity in other codes in the family	-$1.11
369X4	Thrmbc/nfs dialysis circuit	SA015	kit, for percutaneous thrombolytic device (Trerotola)	NF		1	0	Supply removed due to redundancy when used together with supply SD032	-$487.50
369X4	Thrmbc/nfs dialysis circuit	SG095	Hemostatic patch	NF		2	1	Refined supply quantity to what is typical for the procedure	-$35.75
369X5	Thrmbc/nfs dialysis circuit	ED050	PACS Workstation Proxy	NF		104	102	Refined equipment time to conform to changes in clinical labor time	-$0.04
369X5	Thrmbc/nfs dialysis circuit	EL011	room, angiography	NF		87	85	Refined equipment time to conform to changes in clinical labor time	-$10.51
369X5	Thrmbc/nfs dialysis circuit	L037D	RN/LPN/MTA	NF	Follow-up phone calls and prescriptions	6	3	Refined clinical labor time to conform with identical labor activity in other codes in the family	-$1.11
369X5	Thrmbc/nfs dialysis circuit	L037D	RN/LPN/MTA	NF	Coordinate pre-surgery services	6	3	Refined clinical labor time to conform with identical labor activity in other codes in the family	-$1.11

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369X5	Thrmbc/nfs dialysis circuit	L037D	RN/LPN/MTA	F	Schedule space and equipment in facility	6	3	Refined clinical labor time to conform with identical labor activity in other codes in the family	-$1.11
369X5	Thrmbc/nfs dialysis circuit	L037D	RN/LPN/MTA	F	Follow-up phone calls and prescriptions	6	0	Refined clinical labor time to conform with identical labor activity in other codes in the family	-$2.22
369X5	Thrmbc/nfs dialysis circuit	L037D	RN/LPN/MTA	F	Complete preservice diagnostic and referral forms	3	0	Refined clinical labor time to conform with identical labor activity in other codes in the family	-$1.11
369X5	Thrmbc/nfs dialysis circuit	L037D	RN/LPN/MTA	F	Coordinate pre-surgery services	6	3	Refined clinical labor time to conform with identical labor activity in other codes in the family	-$1.11
369X5	Thrmbc/nfs dialysis circuit	L037D	RN/LPN/MTA	NF	Prepare and position pt/ monitor pt/ set up IV	5	3	See preamble text	-$0.74
369X5	Thrmbc/nfs dialysis circuit	SA015	kit, for percutaneous thrombolytic device (Trerotola)	NF		1	0	Supply removed due to redundancy when used together with supply SD032	-$487.50

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
369X5	Thrmbc/nfs dialysis circuit	SG095	Hemostatic patch	NF		2	1	Refined supply quantity to what is typical for the procedure	-$35.75
369X6	Thrmbc/nfs dialysis circuit	ED050	PACS Workstation Proxy	NF		119	117	Refined equipment time to conform to changes in clinical labor time	-$0.04
369X6	Thrmbc/nfs dialysis circuit	EL011	room, angiography	NF		102	100	Refined equipment time to conform to changes in clinical labor time	-$10.51
369X6	Thrmbc/nfs dialysis circuit	L037D	RN/LPN/MTA	NF	Follow-up phone calls and prescriptions	6	3	Refined clinical labor time to conform with identical labor activity in other codes in the family	-$1.11
369X6	Thrmbc/nfs dialysis circuit	L037D	RN/LPN/MTA	NF	Coordinate pre-surgery services	6	3	Refined clinical labor time to conform with identical labor activity in other codes in the family	-$1.11

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
369X6	Thrmbc/nfs dialysis circuit	L037D	RN/LPN/MTA	F	Schedule space and equipment in facility	6	3	Refined clinical labor time to conform with identical labor activity in other codes in the family	-$1.11
369X6	Thrmbc/nfs dialysis circuit	L037D	RN/LPN/MTA	F	Complete preservice diagnostic and referral forms	3	0	Refined clinical labor time to conform with identical labor activity in other codes in the family	-$1.11
369X6	Thrmbc/nfs dialysis circuit	L037D	RN/LPN/MTA	F	Follow-up phone calls and prescriptions	6	0	Refined clinical labor time to conform with identical labor activity in other codes in the family	-$2.22
369X6	Thrmbc/nfs dialysis circuit	L037D	RN/LPN/MTA	F	Coordinate pre-surgery services	6	3	Refined clinical labor time to conform with identical labor activity in other codes in the family	-$1.11
369X6	Thrmbc/nfs dialysis circuit	L037D	RN/LPN/MTA	NF	Prepare and position pt/ monitor pt/ set up IV	5	3	See preamble text	-$0.74
369X6	Thrmbc/nfs dialysis circuit	SA015	kit, for percutaneous thrombolytic device (Trerotola)	NF		1	0	Supply removed due to redundancy when used together with supply SD032	-$487.50
369X6	Thrmbc/nfs dialysis circuit	SA103	stent, vascular, deployment system, Cordis SMART	NF		0	1	Supply item replaces another item; see preamble SD254	$1,645.00

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369X6	Thrmbc/nfs dialysis circuit	SD254	covered stent (VIABAHN, Gore)	NF		1	0	Supply item replaced by another item; see preamble SA103	-$3,768.00
369X6	Thrmbc/nfs dialysis circuit	SG095	Hemostatic patch	NF		2	1	Refined supply quantity to what is typical for the procedure	-$35.75
36X41	Endovenous mchnchem 1st vein	EF014	light, surgical	NF		0	48	Equipment item replaces another item; see preamble text EL015	$0.48
36X41	Endovenous mchnchem 1st vein	EF031	table, power	NF		0	48	Equipment item replaces another item; see preamble text EL015	$0.78
36X41	Endovenous mchnchem 1st vein	EL015	room, ultrasound, general	NF		39	0	Equipment item replaced by another item; see preamble text EQ250	-$54.67
36X41	Endovenous mchnchem 1st vein	EQ250	ultrasound unit, portable	NF		0	48	Equipment item replaces another item; see preamble text EL015	$5.58
36X41	Endovenous mchnchem 1st vein	L037D	RN/LPN/MTA	NF	Prepare room, equipment, supplies	2	0	See preamble text	-$0.74

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
36X41	Endovenous mchnchem 1st vein	L054A	Vascular Technologist	NF	Exam documents scanned into U/S machine. Exam completed in RIS system to generate billing process and to populate images into Radiologist work queue	1	0	See preamble text	-$0.54
36X41	Endovenous mchnchem 1st vein	L054A	Vascular Technologist	NF	Review examination with interpreting MD	2	0	See preamble text	-$1.08
36X41	Endovenous mchnchem 1st vein	L054A	Vascular Technologist	NF	Technologist QCs images in PACS, checking all images, reformats, and dose page	2	0	See preamble text	-$1.08

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
36X41	Endovenous mchnchem 1st vein	L054A	Vascular Technologist	NF	Patient clinical information and questionnaire reviewed by technologist, order from physician confirmed and exam protocoled by radiologist	2	0	See preamble text	-$1.08
36X41	Endovenous mchnchem 1st vein	L054A	Vascular Technologist	NF	Availability of prior images confirmed	2	0	See preamble text	-$1.08
36X41	Endovenous mchnchem 1st vein	SA016	kit, guidewire introducer (Micro-Stick)	NF		1	0	Supply not typically used in this service	-$23.00
36X41	Endovenous mchnchem 1st vein	SH108	Sotradecol Sclerosing Agent	NF		2	1	Refined supply quantity to what is typical for the procedure	-$110.20

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
372X1	Trluml balo angiop 1st art	ED050	PACS Workstation Proxy	NF		91	89	Refined equipment time to conform to changes in clinical labor time	-$0.04
372X1	Trluml balo angiop 1st art	EL011	room, angiography	NF		72	70	Refined equipment time to conform to changes in clinical labor time	-$10.51
372X1	Trluml balo angiop 1st art	L037D	RN/LPN/MTA	NF	Prepare and position patient/ monitor patient/ set up IV	5	3	See preamble text	-$0.74
372X1	Trluml balo angiop 1st art	SB009	drape, sterile, femoral	NF		1	0	Supply item replaced by another item; see preamble SB011	-$15.95
372X1	Trluml balo angiop 1st art	SB011	drape, sterile, fenestrated 16in x 29in	NF		0	1	Supply item replaces another item; see preamble SB009	$0.56

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
372X3	Trluml balo angiop 1st vein	ED050	PACS Workstation Proxy	NF		91	89	Refined equipment time to conform to changes in clinical labor time	-$0.04
372X3	Trluml balo angiop 1st vein	EL011	room, angiography	NF		72	70	Refined equipment time to conform to changes in clinical labor time	-$10.51
372X3	Trluml balo angiop 1st vein	L037D	RN/LPN/MTA	NF	Prepare and position patient/ monitor patient/ set up IV	5	3	See preamble text	-$0.74
372X3	Trluml balo angiop 1st vein	SB009	drape, sterile, femoral	NF		1	0	Supply item replaced by another item; see preamble	-$15.95
372X3	Trluml balo angiop 1st vein	SB011	drape, sterile, fenestrated 16in x 29in	NF		0	1	Supply item replaces another item; see preamble	$0.56

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
47531	Injection for cholangiogram	ED050	PACS Workstation Proxy	NF		51	46	Refined equipment time to conform to established policies for PACS Workstation Proxy	-$0.11
47531	Injection for cholangiogram	EF018	stretcher	NF		87	82	Refined equipment time to conform to established policies for equipment with 4x monitoring time	-$0.03
47531	Injection for cholangiogram	EF027	table, instrument, mobile	NF		87	82	Refined equipment time to conform to established policies for equipment with 4x monitoring time	-$0.01
47531	Injection for cholangiogram	EL011	room, angiography	NF		27	24	Refined equipment time to conform to changes in clinical labor time	-$15.76
47531	Injection for cholangiogram	EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		87	82	Refined equipment time to conform to established policies for equipment with 4x monitoring time	-$0.07
47531	Injection for cholangiogram	EQ032	IV infusion pump	NF		87	82	Refined equipment time to conform to established policies for equipment with 4x	-$0.03

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
								monitoring time	
47531	Injection for cholangiogram	EQ168	light, exam	NF		51	40	Refined equipment time to conform to established policies for non-highly technical equipment	-$0.05
47531	Injection for cholangiogram	L037D	RN/LPN/MTA	NF	Assist physician in performing procedure	15	0	Removed clinical labor associated with moderate sedation; moderate sedation not typical for this procedure	-$5.55
47531	Injection for cholangiogram	L041B	Radiologic Technologist	NF	Clean room/equipment by physician staff	6	3	Refined time to standard for this clinical labor task	-$1.23
47531	Injection for cholangiogram	L051A	RN	NF	Sedate/Apply anesthesia	2	0	Removed clinical labor associated with moderate sedation; moderate sedation not typical for this procedure	-$1.02

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
47532	Injection for cholangiogram	ED050	PACS Workstation Proxy	NF		81	76	Refined equipment time to conform to established policies for PACS Workstation Proxy	-$0.11
47532	Injection for cholangiogram	EF018	stretcher	NF		297	187	See preamble text MS minutes backed out input	-$0.56
47532	Injection for cholangiogram	EF027	table, instrument, mobile	NF		297	187	See preamble text MS minutes backed out input	-$0.16
47532	Injection for cholangiogram	EL011	room, angiography	NF		57	54	Refined equipment time to conform to changes in clinical labor time	-$15.76
47532	Injection for cholangiogram	EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		297	187	See preamble text MS minutes backed out input	-$1.53
47532	Injection for cholangiogram	EQ032	IV infusion pump	NF		297	187	See preamble text MS minutes backed out input	-$0.70

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
47532	Injection for cholangiogram	EQ168	light, exam	NF		81	70	Refined equipment time to conform to established policies for non-highly technical equipment	-$0.05
47532	Injection for cholangiogram	EQ250	ultrasound unit, portable	NF		81	70	Refined equipment time to conform to established policies for non-highly technical equipment	-$1.28
47532	Injection for cholangiogram	L041B	Radiologic Technologist	NF	Clean room/equipment by physician staff	6	3	Refined time to standard for this clinical labor task	-$1.23
47532	Injection for cholangiogram	L051A	RN	NF	Assist Physician in Performing Procedure (CS)	45	0	See preamble text MS minutes backed out input	-$22.95
47532	Injection for cholangiogram	L051A	RN	NF	Monitor pt. following moderate sedation	15	0	See preamble text MS minutes backed out input	-$7.65

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
47532	Injection for cholangiogram	L051A	RN	NF	Sedate/Apply anesthesia	2	0	See preamble text MS minutes backed out input	-$1.02
47532	Injection for cholangiogram	SA044	pack, conscious sedation	NF		1	0	See preamble text MS supply backed out input	-$17.31
47533	Plmt biliary drainage cath	ED050	PACS Workstation Proxy	NF		96	91	Refined equipment time to conform to established policies for PACS Workstation Proxy	-$0.11
47533	Plmt biliary drainage cath	EF018	stretcher	NF		312	187	See preamble text MS minutes backed out input	-$0.64
47533	Plmt biliary drainage cath	EF027	table, instrument, mobile	NF		312	187	See preamble text MS minutes backed out input	-$0.18

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
47533	Plmt biliary drainage cath	EL011	room, angiography	NF		72	69	Refined equipment time to conform to changes in clinical labor time	-$15.76
47533	Plmt biliary drainage cath	EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		312	187	See preamble text MS minutes backed out input	-$1.74
47533	Plmt biliary drainage cath	EQ032	IV infusion pump	NF		312	187	See preamble text MS minutes backed out input	-$0.79
47533	Plmt biliary drainage cath	EQ168	light, exam	NF		96	85	Refined equipment time to conform to established policies for non-highly technical equipment	-$0.05
47533	Plmt biliary drainage cath	EQ250	ultrasound unit, portable	NF		96	85	Refined equipment time to conform to established policies for non-highly technical equipment	-$1.28
47533	Plmt biliary drainage cath	L041B	Radiologic Technologist	NF	Clean room/equipment by physician staff	6	3	Refined time to standard for this clinical labor task	-$1.23

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
47533	Plmt biliary drainage cath	L051A	RN	NF	Assist Physician in Performing Procedure (CS)	60	0	See preamble text MS minutes backed out input	-$30.60
47533	Plmt biliary drainage cath	L051A	RN	NF	Monitor pt. following moderate sedation	15	0	See preamble text MS minutes backed out input	-$7.65
47533	Plmt biliary drainage cath	L051A	RN	NF	Sedate/Apply anesthesia	2	0	See preamble text MS minutes backed out input	-$1.02
47533	Plmt biliary drainage cath	SA044	pack, conscious sedation	NF		1	0	See preamble text MS supply backed out input	-$17.31
47534	Plmt biliary drainage cath	ED050	PACS Workstation Proxy	NF		104	99	Refined equipment time to conform to established policies for PACS Workstation Proxy	-$0.11
47534	Plmt biliary drainage cath	EF018	stretcher	NF		320	187	See preamble text MS minutes backed out input	-$0.68
47534	Plmt biliary drainage cath	EF027	table, instrument, mobile	NF		320	187	See preamble text MS minutes backed out input	-$0.19

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
47534	Plmt biliary drainage cath	EL011	room, angiography	NF		80	77	Refined equipment time to conform to changes in clinical labor time	-$15.76
47534	Plmt biliary drainage cath	EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		320	187	See preamble text MS minutes backed out input	-$1.86
47534	Plmt biliary drainage cath	EQ032	IV infusion pump	NF		320	187	See preamble text MS minutes backed out input	-$0.84
47534	Plmt biliary drainage cath	EQ168	light, exam	NF		104	93	Refined equipment time to conform to established policies for non-highly technical equipment	-$0.05
47534	Plmt biliary drainage cath	EQ250	ultrasound unit, portable	NF		104	93	Refined equipment time to conform to established policies for non-highly technical equipment	-$1.28

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
47534	Plmt biliary drainage cath	L041B	Radiologic Technologist	NF	Clean room/equipment by physician staff	6	3	Refined time to standard for this clinical labor task	-$1.23
47534	Plmt biliary drainage cath	L051A	RN	NF	Assist Physician in Performing Procedure (CS)	68	0	See preamble text MS minutes backed out input	-$34.68
47534	Plmt biliary drainage cath	L051A	RN	NF	Monitor pt. following moderate sedation	15	0	See preamble text MS minutes backed out input	-$7.65
47534	Plmt biliary drainage cath	L051A	RN	NF	Sedate/Apply anesthesia	2	0	See preamble text MS minutes backed out input	-$1.02
47534	Plmt biliary drainage cath	SA044	pack, conscious sedation	NF		1	0	See preamble text MS supply backed out input	-$17.31
47535	Conversion ext bil drg cath	ED050	PACS Workstation Proxy	NF		81	76	Refined equipment time to conform to established policies for PACS Workstation Proxy	-$0.11

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
47535	Conversion ext bil drg cath	EF018	stretcher	NF		297	187	See preamble text MS minutes backed out input	-$0.56
47535	Conversion ext bil drg cath	EF027	table, instrument, mobile	NF		297	187	See preamble text MS minutes backed out input	-$0.16
47535	Conversion ext bil drg cath	EL011	room, angiography	NF		57	54	Refined equipment time to conform to changes in clinical labor time	-$15.76
47535	Conversion ext bil drg cath	EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		297	187	See preamble text MS minutes backed out input	-$1.53
47535	Conversion ext bil drg cath	EQ032	IV infusion pump	NF		297	187	See preamble text MS minutes backed out input	-$0.70
47535	Conversion ext bil drg cath	EQ168	light, exam	NF		81	70	Refined equipment time to conform to established policies for non-highly technical equipment	-$0.05

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
47535	Conversion ext bil drg cath	L041B	Radiologic Technologist	NF	Clean room/equipment by physician staff	6	3	Refined time to standard for this clinical labor task	-$1.23
47535	Conversion ext bil drg cath	L051A	RN	NF	Assist Physician in Performing Procedure (CS)	45	0	See preamble text MS minutes backed out input	-$22.95
47535	Conversion ext bil drg cath	L051A	RN	NF	Monitor pt. following moderate sedation	15	0	See preamble text MS minutes backed out input	-$7.65
47535	Conversion ext bil drg cath	L051A	RN	NF	Sedate/Apply anesthesia	2	0	See preamble text MS minutes backed out input	-$1.02
47535	Conversion ext bil drg cath	SA044	pack, conscious sedation	NF		1	0	See preamble text MS supply backed out input	-$17.31
47536	Exchange biliary drg cath	ED050	PACS Workstation Proxy	NF		56	51	Refined equipment time to conform to established policies for PACS Workstation Proxy	-$0.11

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
47536	Exchange biliary drg cath	EF018	stretcher	NF		152	67	See preamble text MS minutes backed out input	-$0.43
47536	Exchange biliary drg cath	EF027	table, instrument, mobile	NF		152	67	See preamble text MS minutes backed out input	-$0.12
47536	Exchange biliary drg cath	EL011	room, angiography	NF		32	29	Refined equipment time to conform to changes in clinical labor time	-$15.76
47536	Exchange biliary drg cath	EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		152	67	See preamble text MS minutes backed out input	-$1.19
47536	Exchange biliary drg cath	EQ032	IV infusion pump	NF		152	67	See preamble text MS minutes backed out input	-$0.54
47536	Exchange biliary drg cath	EQ168	light, exam	NF		56	45	Refined equipment time to conform to established policies for non-highly technical equipment	-$0.05
47536	Exchange biliary drg cath	L041B	Radiologic Technologist	NF	Clean room/equipment by physician staff	6	3	Refined time to standard for this clinical labor task	-$1.23

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
47536	Exchange biliary drg cath	L051A	RN	NF	Assist Physician in Performing Procedure (CS)	20	0	See preamble text MS minutes backed out input	-$10.20
47536	Exchange biliary drg cath	L051A	RN	NF	Monitor pt. following moderate sedation	15	0	See preamble text MS minutes backed out input	-$7.65
47536	Exchange biliary drg cath	L051A	RN	NF	Sedate/Apply anesthesia	2	0	See preamble text MS minutes backed out input	-$1.02
47536	Exchange biliary drg cath	SA044	pack, conscious sedation	NF		1	0	See preamble text MS supply backed out input	-$17.31
47537	Removal biliary drg cath	ED050	PACS Workstation Proxy	NF		51	46	Refined equipment time to conform to established policies for PACS Workstation Proxy	-$0.11

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
47537	Removal biliary drg cath	EF018	stretcher	NF		87	82	Refined equipment time to conform to established policies for equipment with 4x monitoring time	-$0.03
47537	Removal biliary drg cath	EF027	table, instrument, mobile	NF		87	82	Refined equipment time to conform to established policies for equipment with 4x monitoring time	-$0.01
47537	Removal biliary drg cath	EL011	room, angiography	NF		27	24	Refined equipment time to conform to changes in clinical labor time	-$15.76
47537	Removal biliary drg cath	EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		87	82	Refined equipment time to conform to established policies for equipment with 4x monitoring time	-$0.07
47537	Removal biliary drg cath	EQ032	IV infusion pump	NF		87	82	Refined equipment time to conform to established policies for equipment with 4x monitoring time	-$0.03
47537	Removal biliary drg cath	EQ168	light, exam	NF		51	40	Refined equipment time to conform to established policies for non-highly technical equipment	-$0.05

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
47537	Removal biliary drg cath	L037D	RN/LPN/MTA	NF	Assist physician in performing procedure	15	0	Removed clinical labor associated with moderate sedation; moderate sedation not typical for this procedure	-$5.55
47537	Removal biliary drg cath	L041B	Radiologic Technologist	NF	Clean room/equipment by physician staff	6	3	Refined time to standard for this clinical labor task	-$1.23
47537	Removal biliary drg cath	L051A	RN	NF	Sedate/Apply anesthesia	2	0	Removed clinical labor associated with moderate sedation; moderate sedation not typical for this procedure	-$1.02
47538	Perq plmt bile duct stent	ED050	PACS Workstation Proxy	NF		89	84	Refined equipment time to conform to established policies for PACS Workstation Proxy	-$0.11
47538	Perq plmt bile duct stent	EF018	stretcher	NF		305	187	See preamble text MS minutes backed out input	-$0.60
47538	Perq plmt bile duct stent	EF027	table, instrument, mobile	NF		305	187	See preamble text MS minutes backed out input	-$0.17

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
47538	Perq plmt bile duct stent	EL011	room, angiography	NF		65	62	Refined equipment time to conform to changes in clinical labor time	-$15.76
47538	Perq plmt bile duct stent	EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		305	187	See preamble text MS minutes backed out input	-$1.65
47538	Perq plmt bile duct stent	EQ032	IV infusion pump	NF		305	187	See preamble text MS minutes backed out input	-$0.75
47538	Perq plmt bile duct stent	EQ168	light, exam	NF		89	78	Refined equipment time to conform to established policies for non-highly technical equipment	-$0.05
47538	Perq plmt bile duct stent	L041B	Radiologic Technologist	NF	Clean room/equipment by physician staff	6	3	Refined time to standard for this clinical labor task	-$1.23
47538	Perq plmt bile duct stent	L051A	RN	NF	Assist Physician in Performing Procedure (CS)	53	0	See preamble text MS minutes backed out input	-$27.03
47538	Perq plmt bile duct stent	L051A	RN	NF	Monitor pt. following moderate sedation	15	0	See preamble text MS minutes backed out input	-$7.65
47538	Perq plmt bile duct stent	L051A	RN	NF	Sedate/Apply anesthesia	2	0	See preamble text MS minutes backed out input	-$1.02

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
47538	Perq plmt bile duct stent	SA044	pack, conscious sedation	NF		1	0	See preamble text MS supply backed out input	-$17.31
47538	Perq plmt bile duct stent	SD150	catheter, balloon ureteral (Dowd)	NF		0	2	Supply item replaces another item; see preamble SD152	$130.00
47538	Perq plmt bile duct stent	SD152	catheter, balloon, PTA	NF		2	0	Supply item replaced by another item; see preamble SD150	-$487.00
47539	Perq plmt bile duct stent	ED050	PACS Workstation Proxy	NF		111	106	Refined equipment time to conform to established policies for PACS Workstation Proxy	-$0.11
47539	Perq plmt bile duct stent	EF018	stretcher	NF		327	187	See preamble text MS minutes backed out input	-$0.71
47539	Perq plmt bile duct stent	EF027	table, instrument, mobile	NF		327	187	See preamble text MS minutes backed out input	-$0.20
47539	Perq plmt bile duct stent	EL011	room, angiography	NF		87	84	Refined equipment time to conform to changes in clinical labor time	-$15.76
47539	Perq plmt bile duct stent	EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		327	187	See preamble text MS minutes backed out input	-$1.95
47539	Perq plmt bile duct stent	EQ032	IV infusion pump	NF		327	187	See preamble text MS minutes backed out input	-$0.89

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
47539	Perq plmt bile duct stent	EQ168	light, exam	NF		111	100	Refined equipment time to conform to established policies for non-highly technical equipment	-$0.05
47539	Perq plmt bile duct stent	EQ250	ultrasound unit, portable	NF		111	100	Refined equipment time to conform to established policies for non-highly technical equipment	-$1.28
47539	Perq plmt bile duct stent	L041B	Radiologic Technologist	NF	Clean room/equipment by physician staff	6	3	Refined time to standard for this clinical labor task	-$1.23
47539	Perq plmt bile duct stent	L051A	RN	NF	Assist Physician in Performing Procedure (CS)	75	0	See preamble text MS minutes backed out input	-$38.25
47539	Perq plmt bile duct stent	L051A	RN	NF	Monitor pt. following moderate sedation	15	0	See preamble text MS minutes backed out input	-$7.65
47539	Perq plmt bile duct stent	L051A	RN	NF	Sedate/Apply anesthesia	2	0	See preamble text MS minutes backed out input	-$1.02
47539	Perq plmt bile duct stent	SA044	pack, conscious sedation	NF		1	0	See preamble text MS supply backed out input	-$17.31

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
47539	Perq plmt bile duct stent	SD150	catheter, balloon ureteral (Dowd)	NF		0	2	Supply item replaces another item; see preamble SD152	$130.00
47539	Perq plmt bile duct stent	SD152	catheter, balloon, PTA	NF		2	0	Supply item replaced by another item; see preamble SD150	-$487.00
47540	Perq plmt bile duct stent	ED050	PACS Workstation Proxy	NF		121	116	Refined equipment time to conform to established policies for PACS Workstation Proxy	-$0.11
47540	Perq plmt bile duct stent	EF018	stretcher	NF		337	187	See preamble text MS minutes backed out input	-$0.76
47540	Perq plmt bile duct stent	EF027	table, instrument, mobile	NF		337	187	See preamble text MS minutes backed out input	-$0.21
47540	Perq plmt bile duct stent	EL011	room, angiography	NF		97	94	Refined equipment time to conform to changes in clinical labor time	-$15.76
47540	Perq plmt bile duct stent	EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		337	187	See preamble text MS minutes backed out input	-$2.09
47540	Perq plmt bile duct stent	EQ032	IV infusion pump	NF		337	187	See preamble text MS minutes backed out input	-$0.95

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
47540	Perq plmt bile duct stent	EQ168	light, exam	NF		121	110	Refined equipment time to conform to established policies for non-highly technical equipment	-$0.05
47540	Perq plmt bile duct stent	EQ250	ultrasound unit, portable	NF		121	110	Refined equipment time to conform to established policies for non-highly technical equipment	-$1.28
47540	Perq plmt bile duct stent	L041B	Radiologic Technologist	NF	Clean room/equipment by physician staff	6	3	Refined time to standard for this clinical labor task	-$1.23
47540	Perq plmt bile duct stent	L051A	RN	NF	Assist Physician in Performing Procedure (CS)	85	0	See preamble text MS minutes backed out input	-$43.35
47540	Perq plmt bile duct stent	L051A	RN	NF	Monitor pt. following moderate sedation	15	0	See preamble text MS minutes backed out input	-$7.65
47540	Perq plmt bile duct stent	L051A	RN	NF	Sedate/Apply anesthesia	2	0	See preamble text MS minutes backed out input	-$1.02
47540	Perq plmt bile duct stent	SA044	pack, conscious sedation	NF		1	0	See preamble text MS supply backed out input	-$17.31
47540	Perq plmt bile duct stent	SD150	catheter, balloon ureteral (Dowd)	NF		0	2	Supply item replaces another item; see preamble SD152	$130.00

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
47540	Perq plmt bile duct stent	SD152	catheter, balloon, PTA	NF		2	0	Supply item replaced by another item; see preamble SD150	-$487.00
47541	Plmt access bil tree sm bwl	ED050	PACS Workstation Proxy	NF		96	91	Refined equipment time to conform to established policies for PACS Workstation Proxy	-$0.11
47541	Plmt access bil tree sm bwl	EF018	stretcher	NF		312	187	See preamble text MS minutes backed out input	-$0.64
47541	Plmt access bil tree sm bwl	EF027	table, instrument, mobile	NF		312	187	See preamble text MS minutes backed out input	-$0.18
47541	Plmt access bil tree sm bwl	EL011	room, angiography	NF		72	69	Refined equipment time to conform to changes in clinical labor time	-$15.76
47541	Plmt access bil tree sm bwl	EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		312	187	See preamble text MS minutes backed out input	-$1.74
47541	Plmt access bil tree sm bwl	EQ032	IV infusion pump	NF		312	187	See preamble text MS minutes backed out input	-$0.79
47541	Plmt access bil tree sm bwl	EQ168	light, exam	NF		96	85	Refined equipment time to conform to established policies for non-highly technical equipment	-$0.05

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
47541	Plmt access bil tree sm bwl	EQ250	ultrasound unit, portable	NF		96	85	Refined equipment time to conform to established policies for non-highly technical equipment	-$1.28
47541	Plmt access bil tree sm bwl	L041B	Radiologic Technologist	NF	Clean room/equipment by physician staff	6	3	Refined time to standard for this clinical labor task	-$1.23
47541	Plmt access bil tree sm bwl	L051A	RN	NF	Assist Physician in Performing Procedure (CS)	85	0	See preamble text MS minutes backed out input	-$43.35
47541	Plmt access bil tree sm bwl	L051A	RN	NF	Monitor pt. following moderate sedation	15	0	See preamble text MS minutes backed out input	-$7.65
47541	Plmt access bil tree sm bwl	L051A	RN	NF	Sedate/Apply anesthesia	2	0	See preamble text MS minutes backed out input	-$1.02
47541	Plmt access bil tree sm bwl	SA044	pack, conscious sedation	NF		1	0	See preamble text MS supply backed out input	-$17.31
47542	Dilate biliary duct/ampulla	ED050	PACS Workstation Proxy	NF		30	0	Refined equipment time to conform to changes in clinical labor time	-$0.66

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47542	Dilate biliary duct/ampulla	EF018	stretcher	NF		30	0	See preamble text MS minutes backed out input	-$0.15
47542	Dilate biliary duct/ampulla	EF027	table, instrument, mobile	NF		30	0	See preamble text MS minutes backed out input	-$0.04
47542	Dilate biliary duct/ampulla	EQ011	ECG, 3-channel (with Sp02, NIBP, temp, resp)	NF		30	0	See preamble text MS minutes backed out input	-$0.42
47542	Dilate biliary duct/ampulla	EQ032	IV infusion pump	NF		30	0	See preamble text MS minutes backed out input	-$0.19
47542	Dilate biliary duct/ampulla	EQ168	light, exam	NF		30	0	Refined equipment time to conform to changes in clinical labor time	-$0.13
47542	Dilate biliary duct/ampulla	L051A	RN	NF	Assist Physician in Performing Procedure (CS)	30	0	See preamble text MS minutes backed out input	-$15.30
47542	Dilate biliary duct/ampulla	SD150	catheter, balloon ureteral (Dowd)	NF		0	1	Supply item replaces another item; see preamble SD152	$65.00
47542	Dilate biliary duct/ampulla	SD152	catheter, balloon, PTA	NF		1	0	Supply item replaced by another item; see preamble SD150	-$243.50
47543	Endoluminal bx biliary tree	ED050	PACS Workstation Proxy	NF		30	0	Refined equipment time to conform to changes in clinical labor time	-$0.66

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
47543	Endoluminal bx biliary tree	EF018	stretcher	NF		30	0	See preamble text MS minutes backed out input	-$0.15
47543	Endoluminal bx biliary tree	EF027	table, instrument, mobile	NF		30	0	See preamble text MS minutes backed out input	-$0.04
47543	Endoluminal bx biliary tree	EQ011	ECG, 3-channel (with Sp02, NIBP, temp, resp)	NF		30	0	See preamble text MS minutes backed out input	-$0.42
47543	Endoluminal bx biliary tree	EQ032	IV infusion pump	NF		30	0	See preamble text MS minutes backed out input	-$0.19
47543	Endoluminal bx biliary tree	EQ168	light, exam	NF		30	0	Refined equipment time to conform to changes in clinical labor time	-$0.13
47543	Endoluminal bx biliary tree	L051A	RN	NF	Assist Physician in Performing Procedure (CS)	30	0	See preamble text MS minutes backed out input	-$15.30
47543	Endoluminal bx biliary tree	SD315	Stone basket	NF		1	0	See preamble text	-$417.00
47544	Removal duct glbldr calculi	ED050	PACS Workstation Proxy	NF		45	0	Refined equipment time to conform to changes in clinical labor time	-$0.99

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
47544	Removal duct glbldr calculi	EF018	stretcher	NF		45	0	See preamble text MS minutes backed out input	-$0.23
47544	Removal duct glbldr calculi	EF027	table, instrument, mobile	NF		45	0	See preamble text MS minutes backed out input	-$0.06
47544	Removal duct glbldr calculi	EQ011	ECG, 3-channel (with Sp02, NIBP, temp, resp)	NF		45	0	See preamble text MS minutes backed out input	-$0.63
47544	Removal duct glbldr calculi	EQ032	IV infusion pump	NF		45	0	See preamble text MS minutes backed out input	-$0.28
47544	Removal duct glbldr calculi	EQ168	light, exam	NF		45	0	Refined equipment time to conform to changes in clinical labor time	-$0.19
47544	Removal duct glbldr calculi	L051A	RN	NF	Assist Physician in Performing Procedure (CS)	45	0	See preamble text MS minutes backed out input	-$22.95
47544	Removal duct glbldr calculi	SD150	catheter, balloon ureteral (Dowd)	NF		0	1	Supply item replaces another item; see preamble SD152	$65.00

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
47544	Removal duct glbldr calculi	SD152	catheter, balloon, PTA	NF		1	0	Supply item replaced by another item; see preamble SD150	-$243.50
47544	Removal duct glbldr calculi	SD315	Stone basket	NF		0	1	See preamble text	$417.00
50606	Endoluminal bx urtr rnl plvs	EL014	room, radiographic-fluoroscopic	NF		47	0	Equipment item replaced by another item; see preamble text	-$65.48
50606	Endoluminal bx urtr rnl plvs	EL029	100 KW at 100 kV (DIN6822) generator (for angiography room)	NF		0	47	Equipment item replaces another item; see preamble text EL014	$0.00
50606	Endoluminal bx urtr rnl plvs	EL030	C-arm single plane system, ceiling mounted, integrated multispace (for angiography room)	NF		0	47	Equipment item replaces another item; see preamble text EL014	$0.00
50606	Endoluminal bx urtr rnl plvs	EL031	T motorized rotation, multiple operating modes (for angiography room)	NF		0	47	Equipment item replaces another item; see preamble text EL014	$0.00

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
50606	Endoluminal bx urtr rnl plvs	EL032	real-time digital imaging (for angiography room)	NF		0	47	Equipment item replaces another item; see preamble text EL014	$0.00
50606	Endoluminal bx urtr rnl plvs	EL033	40 cm image intensifier at 40/28/20/14 cm (for angiography room)	NF		0	47	Equipment item replaces another item; see preamble text EL014	$0.00
50606	Endoluminal bx urtr rnl plvs	EL034	30 x 38 image intensifier dynamic flat panel detector (for angiography room)	NF		0	47	Equipment item replaces another item; see preamble text EL014	$0.00
50606	Endoluminal bx urtr rnl plvs	EL035	floor-mounted patient table with floating tabletop designed for angiographic exams and interventions (with peistepping for image intensifiers 13in+)	NF		0	47	Equipment item replaces another item; see preamble text EL014	$0.00
50606	Endoluminal bx urtr rnl plvs	EL036	18 in TFT monitor (for angiography room)	NF		0	47	Equipment item replaces another item; see preamble text EL014	$0.00
50606	Endoluminal bx urtr rnl plvs	EL037	network interface (DICOM) (for angiography room)	NF		0	47	Equipment item replaces another item; see preamble text EL014	$0.00

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50606	Endoluminal bx urtr rnl plvs	EL038	Careposition: radiation free positionong of collimators (for angiography room)	NF		0	47	Equipment item replaces another item; see preamble text EL014	$0.00
50606	Endoluminal bx urtr rnl plvs	EL039	Carewatch: acquisition and monitoring of configurable dose area product (for angiography room)	NF		0	47	Equipment item replaces another item; see preamble text EL014	$0.00
50606	Endoluminal bx urtr rnl plvs	EL040	Carefilter: Cu-prefiltration (for angiography room)	NF		0	47	Equipment item replaces another item; see preamble text EL014	$0.00
50606	Endoluminal bx urtr rnl plvs	EL041	DICOM HIS / RIS (for angiography room)	NF		0	47	Equipment item replaces another item; see preamble text EL014	$0.00
50606	Endoluminal bx urtr rnl plvs	EL042	Control room interface (for angiography room)	NF		0	47	Equipment item replaces another item; see preamble text EL014	$0.00
50606	Endoluminal bx urtr rnl plvs	EL043	Shields, lower body and mavig (for angiography room)	NF		0	47	Equipment item replaces another item; see preamble text EL014	$0.00

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
50606	Endoluminal bx urtr rnl plvs	EL044	Leonardo software (for angiography room)	NF		0	47	Equipment item replaces another item; see preamble text EL014	$0.00
50606	Endoluminal bx urtr rnl plvs	EL045	Fujitsu-Siemens high performance computers (for angiography room)	NF		0	47	Equipment item replaces another item; see preamble text EL014	$0.00
50606	Endoluminal bx urtr rnl plvs	EL046	Color monitors (for angiography room)	NF		0	47	Equipment item replaces another item; see preamble text EL014	$0.00
50606	Endoluminal bx urtr rnl plvs	EL047	Singo modules for dynamic replay and full format images (for angiography room)	NF		0	47	Equipment item replaces another item; see preamble text EL014	$0.00
50606	Endoluminal bx urtr rnl plvs	EL048	Prepared for internal networking and Siemens remote servicing, both hardware and software (for angiography room)	NF		0	47	Equipment item replaces another item; see preamble text EL014	$0.00

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50705	Ureteral embolization/occl	EL014	room, radiographic-fluoroscopic	NF		62	0	Equipment item replaced by another item; see preamble text	-$86.37
50705	Ureteral embolization/occl	EL029	100 KW at 100 kV (DIN6822) generator (for angiography room)	NF		0	62	Equipment item replaces another item; see preamble text EL014	$0.00
50705	Ureteral embolization/occl	EL030	C-arm single plane system, ceiling mounted, integrated multispace (for angiography room)	NF		0	62	Equipment item replaces another item; see preamble text EL014	$0.00
50705	Ureteral embolization/occl	EL031	T motorized rotation, multiple operating modes (for angiography room)	NF		0	62	Equipment item replaces another item; see preamble text EL014	$0.00
50705	Ureteral embolization/occl	EL032	real-time digital imaging (for angiography room)	NF		0	62	Equipment item replaces another item; see preamble text EL014	$0.00
50705	Ureteral embolization/occl	EL033	40 cm image intensifier at 40/28/20/14 cm (for angiography room)	NF		0	62	Equipment item replaces another item; see preamble text EL014	$0.00

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
50705	Ureteral embolization/occl	EL034	30 x 38 image intensifier dynamic flat panel detector (for angiography room)	NF		0	62	Equipment item replaces another item; see preamble text EL014	$0.00
50705	Ureteral embolization/occl	EL035	floor-mounted patient table with floating tabletop designed for angiographic exams and interventions (with peistepping for image intensifiers 13in+)	NF		0	62	Equipment item replaces another item; see preamble text EL014	$0.00
50705	Ureteral embolization/occl	EL036	18 in TFT monitor (for angiography room)	NF		0	62	Equipment item replaces another item; see preamble text EL014	$0.00
50705	Ureteral embolization/occl	EL037	network interface (DICOM) (for angiography room)	NF		0	62	Equipment item replaces another item; see preamble text EL014	$0.00
50705	Ureteral embolization/occl	EL038	Careposition: radiation free positionong of collimators (for angiography room)	NF		0	62	Equipment item replaces another item; see preamble text EL014	$0.00
50705	Ureteral embolization/occl	EL039	Carewatch: acquisition and monitoring of configurable dose area product (for angiography room)	NF		0	62	Equipment item replaces another item; see preamble text EL014	$0.00

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
50705	Ureteral embolization/occl	EL040	Carefilter: Cu-prefiltration (for angiography room)	NF		0	62	Equipment item replaces another item; see preamble text EL014	$0.00
50705	Ureteral embolization/occl	EL041	DICOM HIS / RIS (for angiography room)	NF		0	62	Equipment item replaces another item; see preamble text EL014	$0.00
50705	Ureteral embolization/occl	EL042	Control room interface (for angiography room)	NF		0	62	Equipment item replaces another item; see preamble text EL014	$0.00
50705	Ureteral embolization/occl	EL043	Shields, lower body and mavig (for angiography room)	NF		0	62	Equipment item replaces another item; see preamble text EL014	$0.00
50705	Ureteral embolization/occl	EL044	Leonardo software (for angiography room)	NF		0	62	Equipment item replaces another item; see preamble text EL014	$0.00
50705	Ureteral embolization/occl	EL045	Fujitsu-Siemens high performance computers (for angiography room)	NF		0	62	Equipment item replaces another item; see preamble text EL014	$0.00
50705	Ureteral embolization/occl	EL046	Color monitors (for angiography room)	NF		0	62	Equipment item replaces another item; see preamble text EL014	$0.00
50705	Ureteral embolization/occl	EL047	Singo modules for dynamic replay and full format images (for angiography	NF		0	62	Equipment item replaces another item; see preamble text EL014	$0.00

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
			room)						
50705	Ureteral embolization/occl	EL048	Prepared for internal networking and Siemens remote servicing, both hardware and software (for angiography room)	NF		0	62	Equipment item replaces another item; see preamble text EL014	$0.00
50706	Balloon dilate urtrl strix	EL014	room, radiographic-fluoroscopic	NF		62	0	Equipment item replaced by another item; see preamble text	-$86.37
50706	Balloon dilate urtrl strix	EL029	100 KW at 100 kV (DIN6822) generator (for angiography room)	NF		0	62	Equipment item replaces another item; see preamble text EL014	$0.00
50706	Balloon dilate urtrl strix	EL030	C-arm single plane system, ceiling mounted, integrated multispace (for angiography room)	NF		0	62	Equipment item replaces another item; see preamble text EL014	$0.00
50706	Balloon dilate urtrl strix	EL031	T motorized rotation, multiple operating modes (for angiography room)	NF		0	62	Equipment item replaces another item; see preamble text EL014	$0.00
50706	Balloon dilate urtrl strix	EL032	real-time digital imaging (for angiography room)	NF		0	62	Equipment item replaces another item; see preamble text EL014	$0.00

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50706	Balloon dilate urtrl strix	EL033	40 cm image intensifier at 40/28/20/14 cm (for angiography room)	NF		0	62	Equipment item replaces another item; see preamble text EL014	$0.00
50706	Balloon dilate urtrl strix	EL034	30 x 38 image intensifier dynamic flat panel detector (for angiography room)	NF		0	62	Equipment item replaces another item; see preamble text EL014	$0.00
50706	Balloon dilate urtrl strix	EL035	floor-mounted patient table with floating tabletop designed for angiographic exams and interventions (with peistepping for image intensifiers 13in+)	NF		0	62	Equipment item replaces another item; see preamble text EL014	$0.00
50706	Balloon dilate urtrl strix	EL036	18 in TFT monitor (for angiography room)	NF		0	62	Equipment item replaces another item; see preamble text EL014	$0.00
50706	Balloon dilate urtrl strix	EL037	network interface (DICOM) (for angiography room)	NF		0	62	Equipment item replaces another item; see preamble text EL014	$0.00
50706	Balloon dilate urtrl strix	EL038	Careposition: radiation free positionong of collimators (for angiography room)	NF		0	62	Equipment item replaces another item; see preamble text EL014	$0.00

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
50706	Balloon dilate urtrl strix	EL039	Carewatch: acquisition and monitoring of configurable dose area product (for angiography room)	NF		0	62	Equipment item replaces another item; see preamble text EL014	$0.00
50706	Balloon dilate urtrl strix	EL040	Carefilter: Cu-prefiltration (for angiography room)	NF		0	62	Equipment item replaces another item; see preamble text EL014	$0.00
50706	Balloon dilate urtrl strix	EL041	DICOM HIS / RIS (for angiography room)	NF		0	62	Equipment item replaces another item; see preamble text EL014	$0.00
50706	Balloon dilate urtrl strix	EL042	Control room interface (for angiography room)	NF		0	62	Equipment item replaces another item; see preamble text EL014	$0.00
50706	Balloon dilate urtrl strix	EL043	Shields, lower body and mavig (for angiography room)	NF		0	62	Equipment item replaces another item; see preamble text EL014	$0.00
50706	Balloon dilate urtrl strix	EL044	Leonardo software (for angiography room)	NF		0	62	Equipment item replaces another item; see preamble text EL014	$0.00
50706	Balloon dilate urtrl strix	EL045	Fujitsu-Siemens high performance computers (for angiography room)	NF		0	62	Equipment item replaces another item; see preamble text EL014	$0.00

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
50706	Balloon dilate urtrl strix	EL046	Color monitors (for angiography room)	NF		0	62	Equipment item replaces another item; see preamble text EL014	$0.00
50706	Balloon dilate urtrl strix	EL047	Singo modules for dynamic replay and full format images (for angiography room)	NF		0	62	Equipment item replaces another item; see preamble text EL014	$0.00
50706	Balloon dilate urtrl strix	EL048	Prepared for internal networking and Siemens remote servicing, both hardware and software (for angiography room)	NF		0	62	Equipment item replaces another item; see preamble text EL014	$0.00
51700	Irrigation of bladder	SD024	catheter, Foley	NF		0	1	Supply item replaces another item; see preamble SD030	$7.82
51700	Irrigation of bladder	SD030	catheter, straight	NF		1	0	Supply item replaced by another item; see preamble SD024	-$1.70
51700	Irrigation of bladder	SJ031	leg or urinary drainage bag	NF		0	1	Supply item replaces another item; see preamble SD030	$3.08
51701	Insert bladder catheter	SD024	catheter, Foley	NF		1	0	Supply item replaced by another item; see preamble SD030	-$7.82
51701	Insert bladder catheter	SD030	catheter, straight	NF		0	1	Supply item replaces another item; see preamble SD024	$1.70

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
51701	Insert bladder catheter	SJ031	leg or urinary drainage bag	NF		1	0	Supply item replaced by another item; see preamble SD030	-$3.08
52000	Cystoscopy	EF027	table, instrument, mobile	NF		17	22	Refined equipment time to conform to established policies for scopes	$0.01
52000	Cystoscopy	EF031	table, power	NF		17	22	Refined equipment time to conform to established policies for scopes	$0.08
52000	Cystoscopy	EQ167	light source, xenon	NF		17	22	Refined equipment time to conform to established policies for scopes	$0.14
52000	Cystoscopy	ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart)	NF		17	22	Refined equipment time to conform to established policies for scopes	$0.30
58555	Hysteroscopy dx sep proc	L037D	RN/LPN/MTA	F	Conduct phone calls/call in prescriptions	0	3	Refined time to standard for this clinical labor task	$1.11

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
58562	Hysteroscopy remove fb	L037D	RN/LPN/MTA	F	Conduct phone calls/call in prescriptions	0	3	Refined time to standard for this clinical labor task	$1.11
623X5	Njx interlaminar crv/thrc	SC038	needle, epidural (RK)	NF		1	0	Duplicative; supply is included in conscious sedation pack	-$10.00
623X5	Njx interlaminar crv/thrc	SC051	syringe 10-12ml	NF		1	0	Duplicative; supply is included in conscious sedation pack	-$0.18
623X6	Njx interlaminar crv/thrc	EF018	stretcher	NF		73	75	Refined equipment time to conform to established policies for non-highly technical equipment	$0.01
623X6	Njx interlaminar crv/thrc	EQ211	pulse oximeter w-printer	NF		73	75	Refined equipment time to conform to established policies for non-highly technical equipment	$0.01

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
623X6	Njx interlaminar crv/thrc	SC038	needle, epidural (RK)	NF		1	0	Duplicative; supply is included in conscious sedation pack	-$10.00
623X6	Njx interlaminar crv/thrc	SC051	syringe 10-12ml	NF		2	0	Duplicative; supply is included in conscious sedation pack	-$0.37
623X7	Njx interlaminar lmbr/sac	SC038	needle, epidural (RK)	NF		1	0	Duplicative; supply is included in conscious sedation pack	-$10.00
623X7	Njx interlaminar lmbr/sac	SC051	syringe 10-12ml	NF		1	0	Duplicative; supply is included in conscious sedation pack	-$0.18
623X8	Njx interlaminar lmbr/sac	EF018	stretcher	NF		73	75	Refined equipment time to conform to established policies for non-highly technical equipment	$0.01
623X8	Njx interlaminar lmbr/sac	EQ211	pulse oximeter w-printer	NF		73	75	Refined equipment time to conform to established policies for non-highly technical equipment	$0.01
623X8	Njx interlaminar lmbr/sac	SC038	needle, epidural (RK)	NF		1	0	Duplicative; supply is included in conscious sedation pack	-$10.00

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
623X8	Njx interlaminar lmbr/sac	SC051	syringe 10-12ml	NF		2	0	Duplicative; supply is included in conscious sedation pack	-$0.37
623X9	Njx interlaminar crv/thrc	SC038	needle, epidural (RK)	NF		1	0	Duplicative; supply is included in conscious sedation pack	-$10.00
623X9	Njx interlaminar crv/thrc	SC051	syringe 10-12ml	NF		1	0	Duplicative; supply is included in conscious sedation pack	-$0.18
62X10	Njx interlaminar crv/thrc	EF018	stretcher	NF		73	75	Refined equipment time to conform to established policies for non-highly technical equipment	$0.01
62X10	Njx interlaminar crv/thrc	EQ211	pulse oximeter w-printer	NF		73	75	Refined equipment time to conform to established policies for non-highly technical equipment	$0.01
62X10	Njx interlaminar crv/thrc	SC038	needle, epidural (RK)	NF		1	0	Duplicative; supply is included in conscious sedation pack	-$10.00
62X10	Njx interlaminar crv/thrc	SC051	syringe 10-12ml	NF		2	0	Duplicative; supply is included in conscious sedation pack	-$0.37

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
62X11	Njx interlaminar lmbr/sac	SC038	needle, epidural (RK)	NF		1	0	Duplicative; supply is included in conscious sedation pack	-$10.00
62X11	Njx interlaminar lmbr/sac	SC051	syringe 10-12ml	NF		1	0	Duplicative; supply is included in conscious sedation pack	-$0.18
62X12	Njx interlaminar lmbr/sac	EF018	stretcher	NF		73	75	Refined equipment time to conform to established policies for non-highly technical equipment	$0.01
62X12	Njx interlaminar lmbr/sac	EQ211	pulse oximeter w-printer	NF		73	75	Refined equipment time to conform to established policies for non-highly technical equipment	$0.01
62X12	Njx interlaminar lmbr/sac	SC038	needle, epidural (RK)	NF		1	0	Duplicative; supply is included in conscious sedation pack	-$10.00
62X12	Njx interlaminar lmbr/sac	SC051	syringe 10-12ml	NF		2	0	Duplicative; supply is included in conscious sedation pack	-$0.37

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
70540	Mri orbit/face/neck w/o dye	ED053	Professional PACS Workstation	NF		24	22	Refined equipment time to conform to established policies for PACS Workstation Proxy	-$0.14
70542	Mri orbit/face/neck w/dye	ED053	Professional PACS Workstation	NF		25	23	Refined equipment time to conform to established policies for PACS Workstation Proxy	-$0.14
70543	Mri orbt/fac/nck w/o &w/dye	ED053	Professional PACS Workstation	NF		30	28	Refined equipment time to conform to established policies for PACS Workstation Proxy	-$0.14
77001	Fluoroguide for vein device	ED050	PACS Workstation Proxy	NF		27	25	Refined equipment time to conform to changes in clinical labor time	-$0.04
77001	Fluoroguide for vein device	EL014	room, radiographic-fluoroscopic	NF		24	22	Refined equipment time to conform to changes in clinical labor time	-$2.79

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
77001	Fluoroguide for vein device	L041B	Radiologic Technologist	NF	Prepare room, equipment, supplies	2	0	Add-on code. Additional time for clinical labor task not typical; see preamble text	-$0.82
77002	Needle localization by xray	ED050	PACS Workstation Proxy	NF		27	25	Refined equipment time to conform to changes in clinical labor time	-$0.04
77002	Needle localization by xray	EL014	room, radiographic-fluoroscopic	NF		24	22	Refined equipment time to conform to changes in clinical labor time	-$2.79
77002	Needle localization by xray	L041B	Radiologic Technologist	NF	Prepare room, equipment, supplies	2	0	Add-on code. Additional time for clinical labor task not typical; see preamble text	-$0.82
77003	Fluoroguide for spine inject	ED050	PACS Workstation Proxy	NF		27	25	Refined equipment time to conform to changes in clinical labor time	-$0.04
77003	Fluoroguide for spine inject	EL014	room, radiographic-fluoroscopic	NF		24	22	Refined equipment time to conform to changes in clinical labor time	-$2.79

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
77003	Fluoroguide for spine inject	L041B	Radiologic Technologist	NF	Prepare room, equipment, supplies	2	0	Add-on code. Additional time for clinical labor task not typical; see preamble text	-$0.82
88184	Flowcytometry/ tc 1 marker	ED031	printer, dye sublimation (photo, color)	NF		5	2	Refined equipment time to conform to changes in clinical labor time	-$0.03
88184	Flowcytometry/ tc 1 marker	L033A	Lab Technician	NF	Enter data into laboratory information system, multiparameter analyses and field data entry, complete quality assurance documentation	4	0	Indirect Practice Expense input and/or not individually allocable to a particular patient for a particular service	-$1.32
88184	Flowcytometry/ tc 1 marker	L033A	Lab Technician	NF	Clean room/equipment following	2	1	Refined time to standard for this clinical labor task	-$0.33

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
					procedure (including any equipment maintenance that must be done after the procedure)				
88184	Flowcytometry/ tc 1 marker	L045A	Cytotechnologist	NF	Load specimen into flow cytometer, run specimen, monitor data acquisition, and data modeling, and unload flow cytometer	10	7	Refined clinical labor time to conform with identical labor activity in other codes in the family	-$1.35
88184	Flowcytometry/ tc 1 marker	L045A	Cytotechnologist	NF	Print out histograms, assemble materials with paperwork to pathologists	5	2	Refined time to standard for this clinical labor task	-$1.35

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
88184	Flowcytometry/ tc 1 marker	L045A	Cytotechnologist	NF	Instrument start-up, quality control functions, calibration, centrifugation, maintaining specimen tracking, logs and labeling	15	13	Refined clinical labor time to conform with identical labor activity in other codes in the family	-$0.90
88184	Flowcytometry/ tc 1 marker	SL186	antibody, flow cytometry (each test)	NF		1.6	1	See preamble text	-$5.10
88185	Flowcytometry/tc add-on	ED031	printer, dye sublimation (photo, color)	NF		2	1	Refined equipment time to conform to changes in clinical labor time	-$0.01
88185	Flowcytometry/tc add-on	L033A	Lab Technician	NF	Enter data into laboratory information system, multiparameter analyses	1	0	Indirect Practice Expense input and/or not individually allocable to a particular patient for a particular service	-$0.33

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
					and field data entry, complete quality assurance documentation				
88185	Flowcytometry/tc add-on	SL089	lysing reagent (FACS)	NF		3	2	See preamble text	-$4.49
88185	Flowcytometry/tc add-on	SL186	antibody, flow cytometry (each test)	NF		1.6	1	See preamble text	-$5.10
88321	Microslide consultation	L037B	Histotechnologist	NF	Assemble and deliver slides with paperwork to pathologists	1	0	Clinical labor task redundant with clinical labor task	-$0.37
88323	Microslide consultation	L037B	Histotechnologist	NF	Complete workload recording logs. Collate slides and paperwork. Deliver to pathologist.	0	1	See preamble text	$0.37

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
88323	Microslide consultation	L037B	Histotechnologist	NF	Assemble and deliver slides with paperwork to pathologists	1	0	Clinical labor task redundant with clinical labor task	-$0.37
88323	Microslide consultation	L037B	Histotechnologist	NF	Clean equipment while performing service	1	0	Clinical labor task redundant with clinical labor task	-$0.37
88323	Microslide consultation	SL135	stain, hematoxylin	NF		32	16	See preamble text	-$0.70
88325	Comprehensive review of data	L037B	Histotechnologist	NF	Assemble and deliver slides with paperwork to pathologists	1	0	Clinical labor task redundant with clinical labor task	-$0.37
88325	Comprehensive review of data	L037B	Histotechnologist	NF	Clean Equipment while performing service	1	0	Clinical labor task redundant with clinical labor task	-$0.37

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
88325	Comprehensive review of data	L037B	Histotechnologist	NF	Complete workload recording logs. Collate slides and paperwork. Deliver to pathologist.	0	1	See preamble text	$0.37
88325	Comprehensive review of data	SL135	stain, hematoxylin	NF		32	16	See preamble text	-$0.70
95812	EEG 41-60 minutes	EF003	bedroom furniture (hospital bed, table, reclining chair)	NF		108	99	Refined equipment time to conform to established policies for non-highly technical equipment	-$0.05
95812	EEG 41-60 minutes	EQ017	EEG, digital, prolonged testing system (computer w-remote camera)	NF		108	99	Refined equipment time to conform to established policies for non-highly technical equipment	-$1.32
95812	EEG 41-60 minutes	L047B	REEGT	NF	Perform procedure	62	50	See preamble text	-$5.64
95813	EEG over 1 hour	EF003	bedroom furniture (hospital bed, table, reclining chair)	NF		142	129	Refined equipment time to conform to established policies for non-highly technical equipment	-$0.08

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
95813	EEG over 1 hour	EQ017	EEG, digital, prolonged testing system (computer w-remote camera)	NF		142	129	Refined equipment time to conform to established policies for non-highly technical equipment	-$1.91
95813	EEG over 1 hour	L047B	REEGT	NF	Perform procedure	96	80	See preamble text	-$7.52
96933	Rcm celulr subcelulr img skn	L042A	RN/LPN	NF	Review imaging with interpreting physician	2	0	See preamble text	-$0.84
96934	Rcm celulr subcelulr img skn	EF031	table, power	NF		32	31	Refined equipment time to conform to established policies for non-highly technical equipment	-$0.02
96934	Rcm celulr subcelulr img skn	EQ168	light, exam	NF		32	31	Refined equipment time to conform to established policies for non-highly technical equipment	$0.00
96934	Rcm celulr subcelulr img skn	ES056	reflectance confocal imaging system	NF		32	31	Refined equipment time to conform to established policies for non-highly technical equipment	-$0.37

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
96934	Rcm celulr subcelulr img skn	L042A	RN/LPN	NF	Review imaging with interpreting physician	2	1	See preamble text	-$0.42
96934	Rcm celulr subcelulr img skn	L042A	RN/LPN	NF	Prepare and position pt/ monitor pt/ set up IV	2	1	Add-on code. Additional time for clinical labor task not typical; see preamble text	-$0.42
96934	Rcm celulr subcelulr img skn	L042A	RN/LPN	NF	Patient clinical information and questionnaire reviewed by technologist, order from physician confirmed and exam protocoled by radiologist	2	0	Add-on code. Additional time for clinical labor task not typical; see preamble text	-$0.84
96935	Rcm celulr subcelulr img skn	EF031	table, power	NF		32	31	Refined equipment time to conform to established policies for non-highly technical equipment	-$0.02

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
96935	Rcm celulr subcelulr img skn	EQ168	light, exam	NF		32	31	Refined equipment time to conform to established policies for non-highly technical equipment	$0.00
96935	Rcm celulr subcelulr img skn	ES056	reflectance confocal imaging system	NF		32	31	Refined equipment time to conform to established policies for non-highly technical equipment	-$0.37
96935	Rcm celulr subcelulr img skn	L042A	RN/LPN	NF	Patient clinical information and questionnaire reviewed by technologist, order from physician confirmed and exam protocoled by radiologist	2	0	Add-on code. Additional time for clinical labor task not typical; see preamble text	-$0.84
96935	Rcm celulr subcelulr img skn	L042A	RN/LPN	NF	Prepare and position pt/ monitor pt/ set up IV	2	1	Add-on code. Additional time for clinical labor task not typical; see preamble text	-$0.42

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
96935	Rcm celulr subcclulr img skn	L042A	RN/LPN	NF	Review imaging with interpreting physician	2	0	See preamble text	-$0.84
97X61	Pt eval low complex 20 min	EF028	table, mat, hi-lo, 6 x 8 platform	NF		13	20	Refined equipment time to conform with other codes in the family	$0.07
97X61	Pt eval low complex 20 min	EQ219	rehab and testing system (BTE primus)	NF		5	10	Refined equipment time to conform with other codes in the family	$0.89
97X61	Pt eval low complex 20 min	EQ243	treadmill	NF		5	3	Refined equipment time to conform with other codes in the family	-$0.03
97X61	Pt eval low complex 20 min	L023A	Physical Therapy Aide	NF	Prepare and position pt/ monitor pt/ set up IV	0	2	Refined clinical labor time to conform with identical labor activity in other codes in the family	$0.46
97X61	Pt eval low complex 20 min	L039B	Physical Therapy Assistant	NF	Obtain vital signs	3	5	Refined clinical labor time to conform with identical labor activity in other codes in the family	$0.78
97X61	Pt eval low complex 20 min	L039B	Physical Therapy Assistant	NF	Assist physical therapist with exam/evaluation.	5	10	Refined clinical labor time to conform with identical labor activity in other codes in the family	$1.95

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
					obtain records/measures				
97X61	Pt eval low complex 20 min	L039B	Physical Therapy Assistant	NF	Conduct phone calls/call in prescriptions	0	3	Refined clinical labor time to conform with identical labor activity in other codes in the family	$1.17
97X61	Pt eval low complex 20 min	L039B	Physical Therapy Assistant	NF	Obtain/record medical and medication history, self assessment tools, and fall screening for PT review	5	8	Refined clinical labor time to conform with identical labor activity in other codes in the family	$1.17
97X62	Pt eval mod complex 30 min	L039B	Physical Therapy Assistant	NF	Obtain/record medical and medication history, self assessment tools, and fall screening for PT review	10	8	See preamble text	-$0.78
97X63	Pt eval high complex 45 min	EF028	table, mat, hi-lo, 6 x 8 platform	NF		30	20	Refined equipment time to conform with other codes in the family	-$0.10

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
97X63	Pt eval high complex 45 min	EQ148	kit, hand dexterity, sensory, strength	NF		5	2	Refined equipment time to conform with other codes in the family	-$0.01
97X63	Pt eval high complex 45 min	EQ201	parallel bars, platform mounted	NF		5	0	Refined equipment time to conform with other codes in the family	-$0.02

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
97X63	Pt eval high complex 45 min	EQ243	treadmill	NF		0	3	Refined equipment time to conform with other codes in the family	$0.04
97X63	Pt eval high complex 45 min	L039B	Physical Therapy Assistant	NF	Assist physical therapist with exam/evaluation, obtain records/measures	15	10	Refined clinical labor time to conform with identical labor activity in other codes in the family	-$1.95
97X63	Pt eval high complex 45 min	L039B	Physical Therapy Assistant	NF	Obtain/record medical and medication history, self assessment tools, and fall screening for PT review	12	8	Refined clinical labor time to conform with identical labor activity in other codes in the family	-$1.56
97X63	Pt eval high complex 45 min	SM022	sanitizing cloth-wipe (surface, instruments, equipment)	NF		6	5	Refined supply quantity to conform with other codes in the family	-$0.05
97X64	Pt re-eval est plan care	L039B	Physical Therapy Assistant	NF	Obtain/record medical and medication history, self assessment	5	4	See preamble text	-$0.39

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
					tools, and fall screening for PT review				
97X65	Ot eval low complex 20 min	EF033	table, treatment, hi-lo	NF		0	10	Refined equipment time to conform with other codes in the family	$0.05
97X65	Ot eval low complex 20 min	EL002	environmental module - kitchen	NF		10	11	Refined equipment time to conform with other codes in the family	$0.11
97X65	Ot eval low complex 20 min	EQ068	balance assessment-retraining system (Balance Master)	NF		0	8	Refined equipment time to conform with other codes in the family	$0.43
97X65	Ot eval low complex 20 min	EQ143	kit, ADL	NF		8	11	Refined equipment time to conform with other codes in the family	$0.00

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
97X65	Ot eval low complex 20 min	EQ151	kit, motor coordination	NF		2	3	Refined equipment time to conform with other codes in the family	$0.00
97X65	Ot eval low complex 20 min	EQ152	kit, sensory	NF		2	3	Refined equipment time to conform with other codes in the family	$0.00

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
97X65	Ot eval low complex 20 min	ES057	environmental module - bathroom	NF		0	10	Refined equipment time to conform with other codes in the family	$0.64
97X65	Ot eval low complex 20 min	ES058	kit, vision	NF		0	3	Refined equipment time to conform with other codes in the family	$0.00

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
97X65	Ot eval low complex 20 min	L039B	Physical Therapy Assistant	NF	Obtain vital signs	3	5	Refined clinical labor time to conform with identical labor activity in other codes in the family	$0.78
97X65	Ot eval low complex 20 min	L039B	Physical Therapy Assistant	NF	Obtain measurements	4	6	Refined clinical labor time to conform with identical labor activity in other codes in the family	$0.78
97X65	Ot eval low complex 20 min	L039B	Physical Therapy Assistant	NF	Assist physician in performing procedure (15%)	5	7	Refined clinical labor time to conform with identical labor activity in other codes in the family	$0.78
97X66	Ot eval mod complex 30 min	L039B	Physical Therapy Assistant	NF	Obtain measurements	8	6	See preamble text	-$0.78
97X67	Ot eval high complex 45 min	EF033	table, treatment, hi-lo	NF		15	10	Refined equipment time to conform with other codes in the family	-$0.03

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
97X67	Ot eval high complex 45 min	EL002	environmental module - kitchen	NF		14	11	Refined equipment time to conform with other codes in the family	-$0.34
97X67	Ot eval high complex 45 min	EQ068	balance assessment-retraining system (Balance Master)	NF		0	8	Refined equipment time to conform with other codes in the family	$0.43
97X67	Ot eval high complex 45 min	EQ117	evaluation system for upper extremity-hand (Greenleaf)	NF		5	4	Refined equipment time to conform with other codes in the family	-$0.07
97X67	Ot eval high complex 45 min	EQ143	kit, ADL	NF		15	11	Refined equipment time to conform with other codes in the family	-$0.01
97X67	Ot eval high complex 45 min	EQ185	neurobehavioral status instrument	NF		11	0	Refined equipment time to conform with other codes in the family	-$0.59

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
97X67	Ot eval high complex 45 min	EQ219	rehab and testing system (BTE primus)	NF		5	3	Refined equipment time to conform with other codes in the family	-$0.36
97X67	Ot eval high complex 45 min	ES057	environmental module - bathroom	NF		14	10	Refined equipment time to conform with other codes in the family	-$0.26

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
97X67	Ot eval high complex 45 min	L039B	Physical Therapy Assistant	NF	Obtain measurements	12	6	Refined clinical labor time to conform with identical labor activity in other codes in the family	-$2.34
97X67	Ot eval high complex 45 min	L039B	Physical Therapy Assistant	NF	Assist physician in performing procedure (15%)	9	7	Refined clinical labor time to conform with identical labor activity in other codes in the family	-$0.78

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
97X68	Ot re-eval est plan care	L039B	Physical Therapy Assistant	NF	Obtain measurements	3	2	See preamble text	-$0.39
G0416	Prostate biopsy, any mthd	SL063	eosin y	NF		48	0	Supply item replaced by another item; see preamble SL201	-$38.45

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
G0416	Prostate biopsy, any mthd	SL201	stain, eosin	NF		0	48	Supply item replaces another item; see preamble SL063	$3.24

TABLE 26—INVOICES RECEIVED FOR EXISTING DIRECT PE INPUTS

CPT/HCPCS codes	Item name	CMS code	Current price	Updated price	Percent change	Number of invoices	Estimated non-facility allowed services for HCPCS codes using this item
19030, 19081, 19082, 19281, 19282, 19283, 19284, 77053, 77054, 770X1, 770X2, 770X3.	room, digital mammography.	EL013	168,214.00	362,935.00	116	10	2,294,862
31575, 31576, 31577, 31578, 31579, 317X1, 317X2, 317X3, 31580, 31584, 31587, 315X1, 315X2, 315X3, 315X4, 315X5, 315X6, 190+ other codes.	video system, endoscopy (processor, digital capture, monitor, printer, cart).	ES031	33,232.50	15,045.00	−55	1	1,497,130
58555, 58562, 58563, 58565.	endoscope, rigid, hysteroscopy.	ES009	4,990.50	6,207.50	24	1	672
88323, 88355, 88380, 88381.	stain, eosin	SL201	0.04	0.07	55	5	45,393
88360, 88361	Antibody Estrogen Receptor monoclonal.	SL493	3.19	14.00	339	4	216,208
91110	kit, capsule endoscopy w-application supplies (M2A).	SA005	450.00	520.00	16	1	30,464
91110, 91111	video system, capsule endoscopy (software, computer, monitor, printer).	ES029	17,000.00	12,450.00	−27	1	30,586
91111	kit, capsule, ESO, endoscopy w-application supplies (ESO).	SA094	450.00	472.80	5	1	122
95145, 95146, 95148, 95149.	antigen, venom	SH009	16.67	20.14	21	4	50,772
95147, 95148, 95149	antigen, venom, tri-vespid	SH010	30.22	44.05	46	3	37,955
122 codes	light source, xenon	EQ167	6,723.33	7,000.00	4	1	2,149,616
59 codes	fiberscope, flexible, rhinolaryngoscopy.	ES020	6,301.93	4,250.00	−33	1	581,924

TABLE 27—INVOICES RECEIVED FOR NEW DIRECT PE INPUTS

CPT/HCPCS codes	Item name	CMS code	Average price	Number of invoices	Estimated non-facility allowed services for HCPCS codes using this item
31575, 31579, 317X3, 31580, 31584, 31587, 315X1, 315X2, 315X3, 315X4, 315X5, 315X6.	rhinolaryngoscope, flexible, video, non-channeled.	ES063	8,000.00	1	541,537
31576, 31577, 31578, 317X1, 317X2	rhinolaryngoscope, flexible, video, channeled.	ES064	9,000.00	1	756
31576, 31577, 31578	Disposable biopsy forceps	SD318	26.84	1	574
31579	stroboscopy system	ES065	19,100.00	1	54,466
317X3	Voice Augmentation Gel	SJ090	575.00	1	99
36X41	Claravein Kit	SA122	890.00	1	264
36X41, 364X2	Sotradecol Sclerosing Agent	SH108	110.20	1	528
55700	Biopsy Guide	EQ375	7,000.00	0	85,731
58558	BLADE INCSR 2.9MM	SF059	599.00	1	2,677
58558	Hysteroscopic fluid management system.	EQ378	14,698.38	1	2,677
58558	Hysteroscopic Resection System	EQ379	19,857.50	1	2,677
770X1, 770X2, 770X3	PACS Mammography Workstation	ED054	103,616.47	8	2,274,249
70540, 70542, 70543; over 400 additional codes.	Professional PACS Workstation	ED053	14,616.93	9	32,571,650

TABLE 27—INVOICES RECEIVED FOR NEW DIRECT PE INPUTS—Continued

CPT/HCPCS codes	Item name	CMS code	Average price	Number of invoices	Estimated non-facility allowed services for HCPCS codes using this item
77332	knee wedge/foot block system	EQ376	3,290.00	1	48,831
77333	Thermoplastic tissue bolus 30X30X0.3cm.	SD321	23.90	1	3,493
77333	water bath, digital control	EP120	2,350.00	1	3,493
77333, 77334	Supine Breast/Lung Board	EQ377	5,773.15	1	290,969
77334	Urethane Foaming Agent	SL519	53.50	1	287,476
88184, 88185	flow cytometry analytics software	EQ380	14,000.00	1	1,680,252
95144, 95165	antigen vial transport envelope	SK127	1.50	2	6,464,311
961X1	Beck Depression Inventory, Second Edition (BDI–II).	SK128	2.26	1	1
96416	IV infusion pump, ambulatory	EQ381	2384.45	1	117,248
96931, 96932	Imaging Tray	SA121	34.75	1	5
96931, 96932	adhesive ruler	SK125	9.95	1	5
96931, 96932, 96934, 96935	reflectance confocal imaging system	ES056	98,500.00	1	9
97X66, 97X67, 97X68	environmental module—bathroom	ES057	25,000.00	1	115,107
97X66, 97X67	kit, vision	ES058	410.00	1	86,912
GDDD1	patient lift system	EF045	2,824.33	3	15,115,789
GDDD1	wheelchair accessible scale	EF046	875.92	3	15,115,789
GDDD1	leg positioning system	EF047	1,076.50	3	15,115,789

III. Other Provisions of the Proposed Rule for PFS

A. Chronic Care Management (CCM) and Transitional Care Management (TCM) Supervision Requirements in Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)

In the CY 2016 PFS final rule with comment period (80 FR 71080 through 71088), we finalized policies for payment of CCM services in RHCs and FQHCs. Payment for CCM services in RHCs and FQHCs was effective beginning on January 1, 2016, for RHCs and FQHCs that furnish a minimum of 20 minutes of qualifying CCM services during a calendar month to patients with multiple (two or more) chronic conditions that are expected to last at least 12 months or until the death of the patient, and that would place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline. Payment is made when CPT code 99490 is billed alone or with other payable services on a RHC or FQHC claim, and the rate is based on the PFS national average non-facility payment rate. The requirement that RHC or FQHC services be furnished face-to-face was waived for CCM services furnished to a RHC or FQHC patient because CCM services are not required to be furnished face-to-face.

Medicare payment for TCM services furnished by a RHC or FQHC practitioner was effective January 1, 2013, consistent with the effective date of payment for TCM services under the PFS (77 FR 68978 through 68994; also, see CMS-Pub. 100–02, Medicare Benefit Policy Manual, chapter 13, section 110.4).

TCM services are billable only when furnished within 30 days of the date of the patient's discharge from a hospital (including outpatient observation or partial hospitalization), skilled nursing facility, or community mental health center. Communication (direct contact, telephone, or electronic) with the patient or caregiver must commence within 2 business days of discharge, and a face-to-face visit must occur within 14 days of discharge for moderate complexity decision making (CPT code 99495), or within 7 days of discharge for high complexity decision making (CPT code 99496). The TCM visit is billed on the day that the TCM visit takes place, and only one TCM visit may be paid per beneficiary for services furnished during that 30 day post-discharge period. If the TCM visit occurs on the same day as another billable visit, only one visit may be billed. TCM and CCM cannot be billed during the same time period for the same patient.

In the CY 2016 PFS final rule with comment period (80 FR 71087), we responded to comments requesting that we make an exception to the supervision requirements for auxiliary staff furnishing CCM and TCM services incident to physician services in RHCs and FQHCs (80 FR 71087). Auxiliary staff in RHCs and FQHCs furnish services incident to a RHC or FQHC visit and include nurses, medical assistants, and other clinical staff who work under the direct supervision of a RHC or FQHC practitioner. The commenters suggested that the regulatory language be amended to be consistent with the provision in § 410.26(b)(5) for CCM and TCM services under the PFS, which states that services and supplies furnished incident to CCM and TCM services can be furnished under general supervision of the physician (or other practitioner) when they are provided by clinical staff. It further specifies that the physician (or other practitioner) supervising the auxiliary personnel need not be the same physician (or other practitioner) upon whose professional service the incident to service is based, but only the supervising physician (or other practitioner) may bill Medicare for incident to services. We responded that due to the differences between physician offices and RHCs and FQHCs in their models of care and payment structures, we believe that the direct supervision requirement for services furnished by auxiliary staff is appropriate for RHCs and FQHCs, but that we would consider changing this in future rulemaking if RHCs and FQHCs find that requiring direct supervision presents a barrier to furnishing CCM services.

Since payment for CCM in RHCs and FQHCs began on January 1, 2016, some RHCs and FQHCs have informed us that, in their view, the direct supervision requirement for auxiliary staff has limited their ability to furnish CCM services. Specifically, these RHCs and FQHCs have stated that the direct supervision requirement has prevented them from entering into contracts with third party companies to provide CCM services, especially during hours that they are not open, and that they are unable to meet the CCM requirements within their current staffing and budget constraints.

To bill for CCM services, RHCs and FQHCs must ensure that there is access to care management services on a 24 hour a day, 7 day a week basis. This includes providing the patient with a means to make timely contact with RHC or FQHC practitioners who have access to the patient's electronic care plan to address his or her urgent chronic care needs. The RHC or FQHC must ensure the care plan is available electronically at all times to anyone within the RHC or FQHC who is providing CCM services.

Once the RHC or FQHC practitioner has initiated CCM services and the patient has consented to receiving this service, CCM services can be furnished by a RHC or FQHC practitioner, or by auxiliary personnel, as defined in § 410.26(a)(1), which includes nurses, medical assistants, and other staff working under physician supervision who meet the requirements to provide incident to services. Auxiliary personnel in RHCs and FQHCs must furnish services under direct supervision, which requires that a RHC or FQHC practitioner be present in the RHC or FQHC and immediately available to furnish assistance and direction. The RHC or FQHC practitioner does not need to be present in the room when the service is furnished.

Although many RHCs and FQHCs prefer to furnish CCM and TCM services utilizing existing staff, some RHCs and FQHCs would like to contract with a third party to furnish aspects of their CCM and TCM services, but cannot do so because of the direct supervision requirement. Without the ability to contract with a third party, these RHCs and FQHCs have stated that they find it difficult to meet the CCM requirements for 24 hours a day, 7 days a week access to services.

To enable RHCs and FQHCs to effectively contract with third parties to furnish aspects of CCM and TCM services, we propose to revise § 405.2413(a)(5) and § 405.2415(a)(5) to state that services and supplies furnished incident to TCM and CCM services can be furnished under general supervision of a RHC or FQHC practitioner. The proposed exception to the direct supervision requirement would apply only to auxiliary personnel furnishing TCM or CCM incident to services, and would not apply to any other RHC or FQHC services. The proposed revisions for CCM and TCM services and supplies furnished by RHCs and FQHCs are consistent with § 410.26(b)(5), which allows CCM and TCM services and supplies to be furnished by clinical staff under general supervision when billed under the PFS.

B. FQHC-Specific Market Basket

1. Background

Section 10501(i)(3)(A) of the Affordable Care Act (Pub. L. 111–148 and Pub. L. 111–152) added section 1834(o) of the Act to establish a payment system for the costs of FQHC services under Medicare Part B based on prospectively set rates. In the Prospective Payment System (PPS) for FQHC Final Rule published in the May 2, 2014 **Federal Register** (79 FR 25436), we implemented a methodology and payment rates for the FQHC PPS. The FQHC PPS base payment rate was determined using FQHC cost report and claims data and was effective for FQHC payments from October 1, 2014, through December 31, 2015 (implementation year). The adjusted base payment rate for the implementation year was $158.85 (79 FR 25455). When calculating the FQHC PPS payment, the base payment rate is multiplied by the FQHC geographic adjustment factor (GAF) based on the location of the FQHC, and adjusted for new patients or when an initial preventive physical examination or annual wellness visit are furnished. Beginning on October 1, 2014, FQHCs began to transition to the FQHC PPS based on their cost reporting periods. As of January 1, 2016, all FQHCs are paid under the FQHC PPS.

Section 1834(o)(2)(B)(ii) of the Act requires that the payment for the first year after the implementation year be increased by the percentage increase in the MEI. Therefore, in CY 2016, the FQHC PPS base payment rate was increased by the MEI. The MEI was based on 2006 data from the American Medical Association (AMA) for self-employed physicians and was used in the PFS Sustainable Growth Rate (SGR) formula to determine the conversion factor for physician service payments. (See the CY 2014 PFS final rule (78 FR 74264) for a complete discussion of the 2006-based MEI). Section 1834(o)(2)(B)(ii) of the Act also requires that beginning in CY 2017, the FQHC PPS base payment rate will be increased by the percentage increase in a market basket of FQHC goods and services, or if such an index is not available, by the percentage increase in the MEI.

For CY 2017, we are proposing to create a 2013-based FQHC market basket. The proposed market basket uses Medicare cost report (MCR) data submitted by freestanding FQHCs. In the following discussion, we provide an overview of the proposed market basket and describe the methodologies used to determine the cost categories, cost weights, and price proxies. In addition, we compare the growth rates of the proposed FQHC market basket to the growth rates of the MEI.

2. Overview of the FQHC Market Basket

The 2013-based FQHC market basket is a fixed-weight, Laspeyres-type price index. A Laspeyres price index measures the change in price, over time, of the same mix of goods and services purchased in the base period. Any changes in the quantity or mix of goods and services (that is, intensity) purchased over time relative to a base period are not measured.

The index itself is constructed in three steps. First, a base period is selected (in this proposed rule, the base period is CY 2013), total base period costs are estimated for a set of mutually exclusive and exhaustive cost categories, and the proportion of total costs that each cost category represents is calculated. These proportions are called cost weights. Second, each cost category is matched to an appropriate price or wage variable, referred to as a price proxy. These price proxies are derived from publicly available statistical series that are published on a consistent schedule (preferably at least on a quarterly basis). Finally, the cost weight for each cost category is multiplied by the established price proxy index level. The sum of these products (that is, the cost weights multiplied by their price levels) for all cost categories yields the composite index level of the market basket for the given time period. Repeating this step for other periods produces a series of market basket levels over time. Dividing the composite index level of one period by the composite index level for an earlier period produces a rate of growth in the input price index over that timeframe.

As previously noted, the market basket is described as a fixed-weight index because it represents the change in price over time of a constant mix (quantity and intensity) of goods and services needed to furnish FQHC services. The effects on total costs resulting from changes in the mix of goods and services purchased subsequent to the base period are not measured. For example, a FQHC hiring more nurses to accommodate the needs of patients would increase the volume of goods and services purchased by the FQHC, but would not be factored into the price change measured by a fixed-weight FQHC market basket. Only when the index is rebased would changes in the quantity and intensity be captured, with those changes being reflected in the cost weights. Therefore, we rebase the market baskets periodically so that the cost weights reflect a current mix of goods and services purchased (FQHC inputs) to furnish FQHC services.

3. Creating a FQHC Market Basket

In 2015, we began researching the possibility of creating a FQHC market basket that would be used in place of the MEI to update the FQHC PPS base payment rate annually. An FQHC market basket should reflect the cost structures of FQHCs while the MEI reflects the cost structures of self-employed physician offices. At the time of implementation of the FQHC PPS, a FQHC market basket had not been developed, and therefore, the law stipulated that the FQHC PPS base payment rate be updated by the MEI for the first year after implementation (CY 2016). In subsequent years, the FQHC PPS base payment rate should be annually updated by a FQHC market basket, if available.

The MEI cost weights were derived from data collected by the AMA on the Physician Practice Expense Information Survey (PPIS), since physicians, unlike other Medicare providers, are not required to complete and submit a Medicare Cost Report. FQHCs submit expense data annually on the Medicare Cost Report form CMS–222–92 (OMB No: 0938–0107), "Independent Rural Health Clinic and Freestanding Federally Qualified Health Center Cost Report"; therefore, we were able to estimate relative cost weights specific to FQHCs. We define a "major cost weight" as one calculated using the Medicare cost reports (for example, FQHC practitioner compensation). However, the Medicare cost report data allows multiple methods for reporting detailed expenses, either in detailed cost center lines or more broadly reported in general categories of expenses. An alternative data source is used to disaggregate further residual costs that could not be classified into a major cost category directly using only the Medicare Cost Report data. We estimated the cost weights for each year 2009 through 2013 and found the cost weights from each year to be similar, which provided confidence in the derived cost weights.

In summary, our research over the past year allowed us to evaluate the appropriateness of using freestanding FQHC Medicare cost report data to calculate the major cost weights for a FQHC market basket. We believe that the proposed methodologies described below create a FQHC market basket that reflects the cost structure of FQHCs. Therefore, we believe that the use of this proposed 2013-based FQHC market basket to update FQHC PPS base payment rate would more accurately reflect the actual costs and scope of services that FQHCs furnish compared to the 2006-based MEI.

4. Development of Cost Categories and Cost Weights for the Proposed 2013-Based FQHC Market Basket

a. Use of Medicare Cost Report Data

The proposed 2013-based FQHC market basket consists of eight major cost categories, which were derived from the CY 2013 Medicare cost reports for freestanding FQHCs. These categories are FQHC-Practitioner Compensation, Other Clinical Compensation, Non-Health Compensation, Fringe Benefits, Pharmaceuticals, Fixed Capital, Moveable Capital, and an All Other (Residual) cost category. The All Other (Residual) cost category reflects the costs not captured in the other seven cost categories. The CY 2013 Medicare cost reports include all FQHCs whose cost reporting period began on or after January 1, 2013, and prior to or on December 31, 2013. We selected CY 2013 as the base year because the Medicare cost reports for that year were the most recent, complete set of Medicare cost report data available for FQHCs at the time of development of the cost share weights and proposed 2013-based FQHC market basket. As stated above, we compared the cost share weights from the MCR for CY 2009 through CY 2013 and the CY 2013 weights were consistent with the weights from prior years.

We began with all FQHCs with reporting periods in CY 2013 (that is, between and including January 1, 2013, and December 31, 2013). We then excluded FQHCs missing "total costs" (that is, any FQHC that did not report expenses on Worksheet A, Column 7, Line 62). This edit removed 83 providers from our analysis. Next, we compared the total Medicare allowable costs (that is, total costs eligible for reimbursement under the FQHC PPS) to total costs reported on the Medicare cost report. We kept FQHCs whose Medicare-allowable costs accounted for 60 percent or more of total costs to remove FQHCs whose costs were primarily driven by services not covered under the FQHC benefit. For example, FQHCs that reported a majority of costs for dental services were excluded from the sample. This edit removed 33 FQHCs from our analysis. We used the remaining Medicare cost reports to calculate the costs for the eight major cost categories (FQHC Practitioner Compensation, Other Clinical Compensation, Non-Health Compensation, Fringe Benefits, Pharmaceuticals, Fixed Capital, Moveable Capital, and All Other (Residual) costs).

The resulting 2013-based FQHC market basket cost weights reflect Medicare allowable costs. We propose to define Medicare allowable costs for freestanding FQHC facilities as: Worksheet A, Columns 1 and 2, cost centers lines 1 through 51 but excluding line 20, which is professional liability insurance (PLI). We exclude PLI costs from the total Medicare allowable costs because FQHCs that receive section 330 grant funds also are eligible to apply for medical malpractice coverage under Federally Supported Health Centers Assistance Act (FSHCAA) of 1992 (Pub. L. 102–501) and FSHCAA of 1995 (Pub. L. 104–73 amending section 224 of the Public Health Service Act). Below we derive the eight major cost categories.

(1) *FQHC Practitioner Compensation:* A FQHC practitioner is defined as one of the following occupations: Physicians, NPs, PAs, CNMs, Clinical Psychologist (CPs), and Clinical Social Worker (CSWs). Under certain conditions, a FQHC visit also may be provided by qualified practitioners of outpatient DSMT and MNT when the FQHC meets the relevant program requirements for provision of these services. FQHC Practitioner Compensation costs are derived as the sum of compensation and other costs as reported on Worksheet A; columns 1 and 2; lines 1, 2, 3, 6, 7, 13, 14. The Medicare cost reports also captures "Other" compensation costs (the sum of costs reported on Worksheet A; columns 1 and 2; lines 9, 10, 11, and 15). We allocate a portion of these compensation costs to FQHC Practitioner compensation by multiplying this amount by the ratio of FQHC Practitioner compensation costs to the sum of FQHC Practitioner compensation costs and Other Clinical compensation costs. We believe that the assumption of distributing the costs proportionally is reasonable since there is no additional detail on the specific occupations these compensation costs represent. We also include a proportion of Fringe Benefit

costs as described in section III.B.1.a.iv of this proposed rule.

(2) *Other Clinical Compensation:* Other Clinical Compensation includes any health-related clinical staff who does not fall under the definition of a FQHC practitioner from paragraph (1) (FQHC Practitioner Compensation). Other Clinical Compensation costs are derived as the sum of compensation and other costs as reported on Worksheet A; columns 1 and 2; lines 4, 5, and 8. Similar to the FQHC Practitioner compensation, we also allocate a proportion of the "Other" Clinical compensation costs by multiplying this amount by the ratio of Other Clinical Compensation costs to the sum of FQHC Practitioner Compensation costs and Other Clinical compensation costs. Given the ambiguity in the costs reported on these lines, we believe that the assumption of distributing the costs proportionally is reasonable since there is no additional detail on the specific occupations these compensation costs represent. We also include a proportion of Fringe Benefit costs as described in section III.B.1.a.iv of this proposed rule.

(3) *Non-Health Compensation:* Non-Health Compensation includes compensation costs for Office Staff, Housekeeping & Maintenance, and Pharmacy. Non-Health Compensation costs are derived as the sum of compensation costs as reported on Worksheet A; column 1 only for lines 32 and 51; and Worksheet A; both columns 1 and 2 for line 38. We only use the costs from column 1 for housekeeping and maintenance and pharmacy since we believe that there are considerable costs other than compensation that could be reported for these categories. We use the costs from both column 1 and column 2 for office salaries (line 38) since only salaries or compensation should be reported on this line. We also include a proportion of Fringe Benefit costs as described in section III.B.1.a.iv of this proposed rule.

(4) *Fringe Benefits:* Worksheet A; columns 1 and 2; line 45 of the Medicare cost report captures fringe benefits and payroll tax expenses. We proposed to estimate the fringe benefit cost weight as the fringe benefits costs divided by total Medicare allowable costs. We propose to allocate the Fringe Benefits cost weight to the three compensation cost categories (FQHC practitioner compensation, other clinical compensation, and non-health compensation) based on their relative proportions. The fringe benefits ratio is equal to the compensation cost weight as a percent of the sum of the compensation cost weights for all three types of workers. These allocation ratios are 46 percent, 14 percent, and 40 percent, respectively. Therefore, we propose to allocate 46 percent of the fringe benefits cost weight to the FQHC practitioner cost weight, 14 percent of the fringe benefits cost weight to the clinical compensation cost weight, and 40 percent of the fringe benefits cost weight to the non-health compensation cost weight. Table 28 shows the three compensation category cost weights after the fringe benefit cost weight is allocated for the proposed 2013-based FQHC market basket.

TABLE 28—COMPENSATION CATEGORY COST WEIGHTS AFTER FRINGE BENEFITS ALLOCATION

Cost category	Before fringe benefits allocation (%)	After fringe benefits allocation (%)
FQHC Practitioner Compensation	26.8	31.8
Other Clinical Compensation	8.1	9.5
Non-Health Compensation	23.1	27.4
Fringe Benefits (distribute to comp)	10.7	0.0

We believe that distributing the fringe benefit expenses reported on line 45 using the provider-specific compensation ratios is reasonable.

(5) *Pharmaceuticals:* Drugs and biologicals that are not usually self-administered, and certain Medicare-covered preventive injectable drugs are paid incident to a FQHC visit. Therefore, pharmaceutical costs include the non-compensation costs reported on Worksheet A, column 2, for the pharmacy cost center (line 51). We note that pharmaceutical costs are not included in the MEI since pharmaceutical costs are paid outside of the PFS.

(6) *Fixed Capital:* Fixed capital costs are equal to the sum of costs for rent, interest on mortgage loans, depreciation on buildings and fixtures, and property tax as reported on Worksheet A; columns 1 and 2; lines 26, 28, 30, and 33.

(7) *Moveable Capital:* Moveable capital costs are equal to the sum of costs for depreciation of medical equipment, office equipment, and other equipment as reported on Worksheet A; column 1 and 2; lines 19, 31, and 39.

(8) *All Other (Residual):* After estimating the expenses for the seven cost categories listed above, we summed all remaining costs together for each FQHC to come up with All Other (Residual) costs. The costs included in the All Other (Residual) category include all costs reported for medical supplies, transportation, allowable GME pass through costs, facility insurance, utilities, office supplies, legal, accounting, administrative insurance, telephone, housekeeping & maintenance, nondescript healthcare costs, nondescript facility costs, and nondescript administrative costs.

Although a cost weight for these categories could be obtained directly from the costs reported in that cost center's respective line on the cost report form, some FQHCs reported significant costs in other (specify), or "free form," lines which made it difficult to determine the accuracy of these costs. For example, some FQHCs reported costs only in the free form lines and not in the cost center specific lines, while other FQHCs reported costs in both the cost center specific lines and the free form lines. Since a majority of FQHCs used the free form lines, relying solely on the costs reported in the cost center specific lines for costs could lead to an inaccurate cost weights in the market basket. For example, if a FQHC reported all other healthcare costs in line 21 rather than breaking the healthcare costs into the detailed cost centers (lines 17 through 20.50), then the cost weight for medical supplies could be lower than it should be if we did not allocate the costs reported in the free form lines to medical supplies.

Section III.B.1.b explains the method used to allocate the residual costs to more detailed cost categories.

After we derived costs for the eight major cost categories for each FQHC using the Medicare cost report data as previously described, we addressed data outliers using the following steps. First, we divided the costs for each of the eight categories by total Medicare allowable costs for each FQHC. We then removed those FQHCs whose derived cost weights fell in the top and bottom 5 percent of provider specific derived cost weights. Five percent is the standard trim applied for all CMS market basket cost weights. After these outliers were removed, we summed the costs for each category across all remaining FQHCs. We then divided this by the sum of total Medicare allowable costs across all remaining FQHCs to obtain a cost weight for the proposed 2013-based FQHC market basket for the given category. See Table 29 for the resulting cost weights for these major cost categories that we obtained from the Medicare cost reports.

TABLE 29—MAJOR COST CATEGORIES AS DERIVED FROM MEDICARE COST REPORTS

Cost category	2013 FQHC weight (%)
FQHC Practitioner Compensation	26.8
Other Clinical Compensation	8.1
Non-Health Compensation	23.1
Fringe Benefits (distribute to compensation)	10.7
Fixed Capital	4.5
Moveable Capital	1.7
Non Salary Pharmaceuticals	5.1
All Other (Residual)	20.1

Totals may not sum to 100.0% due to rounding.

b. Derivation of Detailed Cost Categories From the All Other (Residual) Cost Weight

The All Other Residual cost weight was derived from summing all expenses reported on the Medicare cost report Worksheet A, columns 1 and 2 for medical supplies (line 17), transportation (line 18), allowable GME pass through costs (line 20.50), facility insurance (line 27), utilities (line 29), office supplies (line 40), legal (line 41), accounting (line 42), administrative insurance (line 43), telephone (line 44), non-compensation housekeeping & maintenance (line 32, column 2 only), nondescript healthcare costs (lines 21–23), nondescript facility costs (lines 34–36), and nondescript administrative costs (lines 54–56).

To further divide the ''All Other'' residual cost weight (20.1 percent) estimated from the CY 2013 Medicare cost report data into more detailed cost categories, we propose to use the relative cost shares from the 2006-based MEI for nine detailed cost categories: Utilities; Miscellaneous Office Expenses; Telephone; Postage; Medical Equipment; Medical Supplies; Professional, Scientific, & Technical Services; Administrative & Facility Services; and Other Services. For example, the Utilities cost represents 7 percent of the sum of the 2006-based MEI ''All Other'' cost category weights; therefore, the Utilities cost weight would represent 7 percent of the proposed 2013-based FQHC market basket's ''All Other'' cost category (20.066 percent), yielding a ''final'' Utilities proposed cost weight of 1.4 percent in the proposed 2013-based LTCH market basket (7 percent * 20.1 percent = 1.4 percent).

Table 30 shows the cost weight for each matching category from the 2006-based MEI, the percent each cost category represents of the 2006-based MEI ''All Other'' cost weight, and the resulting proposed 2013-based FQHC market basket cost weights for detailed cost categories.

TABLE 30—PROPOSED DETAILED FQHC COST CATEGORY WEIGHTS

Proposed FQHC detailed cost categories	2006-based MEI cost weights (%)	Percent of the 2006-based MEI ''All Other'' cost weight (%)	Proposed 2013-based FQHC detailed cost weights (%)
Total All Other (Residual)	17.976	100.000	20.1
Utilities	1.266	7.0	1.4
Miscellaneous Office Expenses	2.478	13.8	2.8
Telephone	1.501	8.4	1.7
Postage	0.898	5.0	1.0
Medical Equipment	1.978	11.0	2.2
Medical supplies	1.760	9.8	2.0
Professional, Scientific, & Tech. Services	2.592	14.4	2.9
Administrative & Facility Services	3.052	17.0	3.4
Other Services	2.451	13.6	2.7

FQHCs have liberty in how and where certain costs are reported on the Medicare cost report form. We believe that, given the ambiguity in how the data are reported for these overhead cost centers on the FQHC cost report form, relying on the relative shares determined from the MEI is reasonable. We hope that future cost data from the upcoming revised FQHC cost report form will allow us to better estimate the detailed cost weights for these categories directly. All FQHCs will report costs on the new forms for cost report periods for CY 2016 expenses. For details regarding how the 2006-based MEI cost categories were derived, see the CY 2011 PFS final rule with comment period (75 FR 73262 through 73267). The following is a description of the types of expenses included in detailed cost categories derived from the All Other (Residual) cost category:

- *Utilities:* Includes expenses classified in the fuel, oil and gas, water and sewage, and electricity industries. These types of industries are classified in NAICS and include NAICS 2211 (Electric power generation, transmission, and distribution), 2212 (Natural gas distribution), and 2213 (Water, sewage, and other systems).
- *Miscellaneous Office Expense:* Includes expenses for office expenses not reported in other categories, miscellaneous expenses, included but not limited to, paper (such as paper towels), printing (such as toner for printers), miscellaneous chemicals (such as soap and hand sanitizer).
- *Telephone:* Includes expenses classified in NAICS 517

(Telecommunications) and NAICS 518 (Internet service providers), and NAICS 515 (Cable and other subscription programming). Telephone service, which is one component of the Telecommunications expenses, accounts for the majority of the expenditures in this cost category.

- *Postage:* Includes expenses classified in NAICS 491 (Postal services) and NAICS 492 (Courier services).
- *Medical Equipment Expenses:* Includes the expenses related to maintenance contracts, and the leases or rental of medical equipment used in diagnosis or treatment of patients. It would also include the expenses for any medical equipment that was purchased in a single year and not financed.
- *Medical Supplies Expenses:* Includes the expenses related to medical supplies such as sterile gloves, needles, bandages, specimen containers, and catheters. We note that the Medical Supply cost category does not include expenses related to pharmaceuticals (drugs and biologicals).
- *Professional, Scientific, & Technical Services:* Includes the expenses for any professional services purchased from an outside agency or party and could include fees including but not limited to, legal, marketing, professional association memberships, licensure fees, journal fees, continuing education.
- *Administrative & Facility Services:* Includes the expenses for any administrative and facility services purchased from an outside agency or party and could include fees including but not limited to, accounting, billing, office management services, security services, transportation services, landscaping, or professional car upkeep.
- *Other Services:* Includes other service expenses including, but not limited to, nonresidential maintenance and repair, machinery repair, janitorial, and security services.

Table 31 shows the proposed cost categories and weights for the 2013-based FQHC market basket. The resulting cost weights include combining the cost weights derived from the Medicare Cost Report Data (shown in Table 29), distributing the fringe benefits weight across the three compensation cost categories (shown in Table 28), and disaggregating the residual cost weight into detailed cost categories (shown in Table 30). Additionally, we compare the cost weights of the proposed 2013-based FQHC market basket to the cost weights in the 2006-based MEI, where we have grouped the cost weights from the MEI to align with the FQHC proposed cost categories.

TABLE 31—PROPOSED FQHC MARKET BASKET AND MEI, COST CATEGORIES, COST WEIGHTS

FQHC cost category	2013 FQHC weight (percent)	2006 MEI weight (percent)	MEI cost category
FQHC Market Basket	100.0	100.000	MEI.
Total Compensation	68.7	67.419	Total Compensation.
FQHC Practitioner Compensation	31.7	50.866	Physician Compensation.
Other Clinical Compensation	9.5	6.503	Other Clinical Compensation.
Non-health Compensation	27.4	10.050	Non-health Compensation.
All Other Products	16.1	14.176	All Other Products.
Utilities	1.4	1.266	Utilities.
Miscellaneous Office Expenses	2.8	2.478	Miscellaneous Office Expenses.
Telephone	1.7	1.501	Telephone.
Postage	1.0	0.898	Postage.
Medical Equipment	2.2	1.978	Medical Equipment.
Medical Supplies	2.0	1.760	Medical Supplies.
Professional Liability Insurance	....	4.295	Professional Liability Insurance.
Pharmaceuticals	5.1	....	Pharmaceuticals.
All Other Services	9.0	8.095	All Other Services.
Professional, Scientific & Technical Services	2.9	2.592	Professional, Scientific & Technical Services.
Administrative & Facility Services	3.4	3.052	Administrative & Facility Services.
Other Services	2.7	2.451	Other Services.
Capital	6.1	10.310	Capital.
Fixed Capital	4.5	8.957	Fixed Capital.
Moveable Capital	1.7	1.353	Moveable Capital.

Although the overall cost structure of the MEI, the index currently used to update the FQHC PPS base payment, is similar to the proposed FQHC cost structure, there are a few key differences.

First, though total compensation costs in the proposed FQHC market basket and the MEI are each approximately 67–68 percent of total costs, non-health compensation accounts for a larger share of compensation costs in the FQHC setting than in the self-employed physician office. Likewise, physician compensation accounts for a larger percentage of costs in the MEI than FQHC practitioner compensation accounts for in the proposed FQHC market basket.

Second, the proposed FQHC market basket includes a cost category for pharmaceuticals, while drug costs are excluded from the MEI. Drug costs are an expense in the FQHC PPS base payment rate since drugs and biologicals that are not usually self-administered, and certain Medicare-covered preventive injectable drugs are paid incident to a visit while drug costs are reimbursed separately under the PFS.

Third, as mentioned previously, PLI expenditures are excluded from the proposed FQHC market basket since most FQHCs PLI costs are covered under the Federal Tort Claims Act, while in the MEI the PLI costs are a significant expense for self-employed physicians. Finally, fixed capital expenses, which include costs such as office rent and depreciation, are about half of the share in the FQHC market basket as they are in the MEI.

c. Selection of Price Proxies for the Proposed 2013-Based FQHC Market Basket

After establishing the 2013 cost weights for the proposed FQHC market basket, an appropriate price proxy was selected for each cost category. The proposed price proxies are chosen from a set of publicly available price indexes that best reflect the rate of price change for each cost category in the FQHC market basket. All of the proxies for the proposed 2013-based FQHC market basket are based on indexes published by the Bureau of Labor Statistics (BLS) and are grouped into one of the following BLS categories:

- *Producer Price Indexes:* Producer Price Indexes (PPIs) measure price changes for goods sold in markets other than the retail market. PPIs are preferable price proxies for goods and services that businesses purchase as inputs. For example, we are proposing to use a PPI for prescription drugs, rather than the Consumer Price Index (CPI) for prescription drugs, because healthcare providers generally purchase drugs directly from a wholesaler. The PPIs that we are proposing to use measure price changes at the final stage of production.
- *Consumer Price Indexes:* CPIs measure change in the prices of final goods and services bought by the typical consumer. Because they may not represent the price encountered by a producer, we are proposing to use CPIs only if an appropriate PPI is not available, or if the expenditures are more like those faced by retail consumers in general rather than by purchasers of goods at the wholesale level.
- *Employment Cost Indexes:* Employment Cost Indexes (ECIs) measure the rate of change in employee wage rates and employer costs for employee benefits per hour worked. These indexes are fixed-weight indexes and strictly measure the change in wage rates and employee benefits per hour. Appropriately, they are not affected by shifts in employment mix.

We evaluate the price proxies using the criteria of reliability, timeliness, availability, and relevance. Reliability indicates that the index is based on valid statistical methods and has low sampling variability. Timeliness implies that the proxy is published regularly, preferably at least once a quarter. Availability means that the proxy is publicly available. Finally, relevance means that the proxy is applicable and representative of the cost category weight to which it is applied. We believe the proposed PPIs, CPIs, and ECIs selected meet these criteria.

Table 32 lists all price proxies that we are proposing to use for the 2013-based FQHC market basket. Below is a detailed explanation of the price proxies that we are proposing for each cost category weight. We note that many of the proxies that we are proposing for the 2013-based FQHC market basket are the same as those used for the 2006-based MEI.

(1) *FQHC Practitioner Compensation:* We are proposing to use the ECI for Total Compensation for Private Industry Workers in Professional and Related) (BLS series code CIU2010000120000I) to measure price growth of this category. There is no specific ECI for physicians and, therefore, similar to the MEI, we are proposing to use an index that is based on professionals that receive advanced training. We note that the 2006-based MEI has a separate cost category for Physician Wages and Salaries and Physician Benefits. For these cost categories, the MEI uses the ECI for Wages and Salaries and ECI for Benefits for Professional and Related Occupations.

(2) *Other Clinical Compensation:* We are proposing to use the ECI for Total Compensation for all Civilian Workers in Health Care and Social Assistance (BLS series code CIU1016200000000I) to measure the price growth of this cost category. This cost category consists of compensation costs for Nurses, Laboratory Technicians, and all other health staff not included in the FQHC practitioner compensation category. Based on the clinical composition of these workers, we believe that the ECI for health-related workers is an appropriate proxy to measure compensation price pressures for these workers. The MEI uses the ECI for Wages and Salaries and benefits for Hospitals.

(3) *Non-Health Compensation:* We are proposing to use the ECI for Total Compensation for Private Industry Workers in Office and Administrative Support (BLS series code CIU2010000220000I) to measure the price growth of this cost category. The Non-health compensation cost weight is predominately attributable to administrative and facility type occupations, as reported in the data from the Medicare cost reports. We note the MEI has a composite index of four price proxies, with the majority of the composite index accounted for by administrative occupations, proxied by the ECI for Wages & Salaries of Office and Administrative Support (Private).

(4) *Utilities:* We are proposing to use the CPI for Fuel and Utilities (BLS series code CUUR0000SAH2) to measure the price growth of this cost category. This is the same proxy used in the 2006-based MEI.

(5) *Miscellaneous Office Expenses:* We are proposing to use the CPI for All Items Less Food and Energy (BLS series code CUUR0000SA0L1E) to measure the price growth of this cost category. We believe that using the CPI for All Items Less Food and Energy avoids double counting of changes in food and energy prices already captured elsewhere in the market basket. We note the MEI does not have a separate cost category for miscellaneous office expenses.

(6) *Telephone Services:* We are proposing to use the CPI for Telephone Services (BLS series code CUUR0000SEED) to measure the price growth of this cost category. This is the same price proxy used in the 2006-based MEI.

(7) *Postage:* We are proposing to use the CPI for Postage (BLS series code CUUR0000SEEC01) to measure the price growth of this cost category. This is the same proxy used in the 2006-based MEI.

(8) *Medical Equipment:* We are proposing to use the PPI Commodities for Surgical and Medical Instruments (BLS series code WPU1562) as the price proxy for this category. This is the same proxy used in the current 2006-based MEI.

(9) *Medical Supplies:* We are proposing to use a 50/50 blended index comprised of the PPI Commodities for Medical and Surgical Appliances and Supplies (BLS series code WPU156301) and the CPI–U for Medical Equipment and Supplies (BLS series code CUUR0000SEMG). The 50/50 blend is used in all market baskets where we do not have an accurate split available. We believe FQHCs purchase the types of supplies contained within these proxies, including such items as bandages, dressings, catheters, intravenous equipment, syringes, and other general disposable medical supplies, via wholesale purchase, as well as at the retail level. Consequently, we are proposing to combine the two aforementioned indexes to reflect those modes of purchase. This is the same proxy used in the 2006-based MEI.

(10) *Pharmaceuticals:* We are proposing to use the PPI Commodities for Pharmaceuticals for Human Use, Prescription (BLS series code WPUSI07003) to measure the price growth of this cost category. We note the MEI does not have a separate cost category for Pharmaceuticals. This price proxy is used to measure prices of Pharmaceuticals in other CMS market baskets, such as 2010-based Inpatient Prospective Payment System and 2010-based Skilled Nursing Facility market baskets.

(11) *Professional, Scientific, & Technical Services:* We are proposing to use the ECI for Total Compensation for Private Industry Workers in Professional, Scientific, and Technical Services (BLS series code CIU2015400000000I) to measure the price growth of this cost category. This

is the same proxy used in the 2006-based MEI.

(12) *Administrative & Facility Services:* We are proposing to use the ECI Total Compensation for Private Industry Workers in Office and Administrative Support (BLS series code CIU2010000220000I) to measure the price growth of this cost category. This is the same price proxy used in the 2006-based MEI.

(13) *Other Services:* We are proposing to use the ECI for Total Compensation for Private Industry Workers in Service Occupations (BLS series code CIU2010000300000I) to measure the price growth of this cost category. This is the same price proxy used in the 2006-based MEI.

(14) *Fixed Capital:* We are proposing to use the PPI Industry for Lessors of Nonresidential Buildings (BLS series code PCU531120531120) to measure the price growth of this cost category. This is the same price proxy used in the 2006-based MEI. We believe this is an appropriate proxy since fixed capital expenses in FQHCs should reflect inflation for the rental and purchase of business office space.

(15) *Moveable Capital:* We are proposing to use the PPI Commodities for Machinery and Equipment (series code WPU11) to measure the price growth of this cost category as this cost category represents nonmedical moveable equipment. This is the same proxy used in the 2006-based MEI.

Table 32 lists the proposed price proxies for each cost category in the proposed FQHC market basket.

TABLE 32—PROPOSED COST CATEGORIES AND PRICE PROXIES FOR THE FQHC MARKET BASKET

Cost category	FQHC price proxies
FQHC Practitioner Compensation	ECI—for Total Compensation for Private Industry Workers in Professional and Related.
Other Clinical Compensation	ECI—for Total Compensation for all Civilian Workers in Health Care and Social Assistance.
Non-health Compensation	ECI—for Total Compensation for Private Industry Workers in Office and Administrative Support.
Utilities	CPI–U for Fuels and Utilities.
Miscellaneous Office Expense	CPI–U for All Items Less Food And Energy.
Telephone	CPI–U for Telephone.
Postage	CP–U for Postage.
Medical Equipment	PPI Commodities for Surgical and Medical Instruments.
Medical supplies	Blend: PPI Commodities for Medical and Surgical Appliances and Supplies and CPI for Medical Equipment and Supplies.
Pharmaceuticals	PPI Commodities for Pharmaceuticals for Human Use, Prescription.
Professional, Scientific, and Technical Services	ECI—for Total Compensation for Private Industry Workers in Professional, Scientific, and Technical Services.
Administrative & Facility Services	ECI—for Total Compensation for Private Industry Workers in Office and Administrative Support.
Other Services	ECI—for Total compensation for Private industry workers in Service Occupations.
Fixed Capital	PPI Industry—for Lessors of nonresidential buildings.
Moveable Capital	PPI Commodities—for Machinery and Equipment.

d. Inclusion of Multi-Factor Productivity in the Proposed FQHC Market Basket

Section 1834(o)(2)(B)(ii) of the Act describes the methods for determining updates to FQHC PPS payment. After the first year of implementation, the FQHC PPS base payment rate must be increased by the percentage increase in the MEI. In subsequent years, the FQHC PPS base payment rate shall be increased by the percentage increase in a market basket of FQHC goods and services as established through regulations or, if not available, the MEI published in the PFS final rule.

The MEI published in the PFS final rule has a productivity adjustment. The MEI has been adjusted for changes in productivity since its inception. In the CY 2003 PFS final rule with comment period (67 FR 80019), we implemented a change in the way the MEI was adjusted to account for changes in productivity. The MEI used for the 2003 physician payment update incorporated changes in the 10-year moving average of private nonfarm business (economy-wide) multifactor productivity. Previously, the index incorporated changes in productivity by adjusting the labor portions of the index by the 10-year moving average of private nonfarm business (economy-wide) labor productivity.

In 2012, we convened the MEI Technical Panel to review all aspects of the MEI including inputs, input weights, price-measurement proxies, and productivity adjustment. For more information regarding the MEI Technical Panel, see the CY 2014 PFS final rule with comment period (78 FR 74264). The MEI Technical Panel was asked to review the approach of adjusting the MEI by the 10-year moving average of private nonfarm business productivity. As described in the CY 2014 PFS final rule with comment period (78 FR 74271), the MEI Technical Panel concluded in Finding 5.1 that "such an adjustment continues to be appropriate. This adjustment prevents 'double counting' of the effects of productivity improvements, which would otherwise be reflected in both (i) the increase in compensation and other input price proxies underlying the MEI, and (ii) the growth in the number of physician services performed per unit of input resources, which results from advances in productivity by individual physician practices."

We are proposing to include a productivity adjustment similar to the MEI in the proposed FQHC market basket. We believe that applying a productivity adjustment is appropriate because this would be consistent with the MEI, which has an embedded productivity adjustment. We note that the MEI Technical Panel concluded that a productivity adjustment is appropriate for the MEI given the type of services performed in physician's offices. Specifically, the MEI Technical Panel report states that "The input price increases within the MEI are reflected in the price proxies, such as changes in wages and benefits. Wages increase, in part, due to the ability of workers to increase the amount of output per unit of input. Absent a productivity adjustment in the MEI, physicians would be receiving increased payments resulting both from their ability to increase their individual outputs and from the productivity gains already reflected in the wage proxies used in the index. The productivity adjustment used in the MEI ensures the productivity gains reflected in increased outputs are not double counted, or paid for twice. Currently, the productivity adjustment in the MEI is based on changes in economy-wide productivity based on the rationale that the price proxy for physician income reflects changes in economy-wide wages. Implicitly, this assumes physicians can achieve the same level of productivity as the average general wage earner.'' We believe that the services performed in FQHC facilities are similar to those covered by the MEI, and therefore, a productivity adjustment is appropriate to avoid double counting of the effects of productivity improvements.

We propose to use the most recent estimate of the 10-year moving average of changes in annual private nonfarm business (economy-wide) multifactor productivity (MFP), which is the same measure of MFP used in the MEI. The BLS publishes the official measure of private nonfarm business MFP. (See *http://www.bls.gov/mfp* for the published BLS historical MFP data). For the final FQHC market basket update, we propose to use the most recent historical estimate of annual MFP as published by the BLS. Generally, the most recent historical MFP estimate is lagged two years from the payment year. Therefore, we propose to use the 2015 MFP as published by BLS in the CY2017 FQHC market basket update.

We note that MFP is derived by subtracting the contribution of labor and capital input growth from output growth. Since at the time of the proposed rule the 2015 MFP has not been published by BLS, we rely on a projection of MFP. The projection of MFP is currently produced by IHS Global Insight (IGI), a national economic forecasting firm with which CMS contracts to forecast the components of the market basket and MFP. A complete description of the MFP projection methodology is available at *http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/MarketBasketResearch.html.*

Using IGI's first quarter 2016 forecast, the productivity adjustment for CY 2017 (the 10-year moving average of MFP for the period ending CY 2015) is projected to be 0.4 percent. If more recent data are subsequently available (for example, a more recent estimate of the market basket and MFP adjustment), we would use such data to determine the CY 2017 increase in the proposed FQHC market basket in the final rule.

5. CY 2017 Proposed Market Basket Update: Proposed CY 2017 FQHC Market Basket Update Compared to the MEI Update for CY 2017

For CY 2017, we are proposing to use the proposed 2013-based FQHC market basket increase factor to update the FQHC PPS base payment rate. Consistent with CMS practice, we estimated the market basket update for the FQHC PPS based on the most recent forecast from IGI. Identical to the MEI, we are proposing to use the update based on the most recent historical data available at the time of publication of the final rule. For example, the final CY 2017 FQHC update would be based on the four-quarter moving-average percent change of the FQHC market basket through the second quarter of 2016 (based on the final rule's statutory publication schedule). For the proposed rule, we do not have the second quarter of 2016 historical data and, therefore, we will use the most recent projection available.

Based on IGI's first quarter 2016 forecast with historical data through the fourth quarter of 2015, the projected proposed FQHC market basket increase factor for CY 2017 would be 1.7 percent. This reflects a 2.1-percent increase of FQHC input prices and a 0.4-percent adjustment for productivity. We are also proposing that if more recent data are subsequently available (for example, a more recent estimate of the market basket or MFP) we would use such data, to determine the CY 2017 update in the final rule.

For comparison, the 2006-based MEI is projected to be 1.3 percent in CY 2017; this estimate is based on IGI's first quarter 2016 forecast (with historical data through the fourth quarter of 2015). Table 33 compares the proposed 2013-based FQHC market basket updates and the 2006-based MEI market basket updates for CY 2017.

TABLE 33—FQHC MARKET BASKET AND MEI, COST CATEGORIES, COST WEIGHTS, MFP, AND CY 2017 UPDATE

FQHC cost category	CY 2017 Update		MEI cost category
	(percent)	(percent)	
FQHC Market Basket	1.7	1.3	MEI.
Productivity adjustment	0.4	0.4	Productivity adjustment.
FQHC Market Basket (unadjusted)	2.1	1.7	MEI (unadjusted).
Total Compensation	2.1	2.0	Total Compensation.
FQHC Practitioner Comp.	1.9	2.0	Physician Compensation.
Other Clinical Compensation	1.9	2.0	Other Clinical Compensation.
Non-health Compensation	2.4	2.4	Non-health Compensation.
All Other Products	2.6	−0.6	All Other Products.
Utilities	−3.9	−3.9	Utilities.
Miscellaneous Office Expenses	2.0	−1.7	Miscellaneous Office Expenses.
Telephone	0.4	0.4	Telephone.
Postage	0.3	0.3	Postage.
Medical Equipment	1.2	1.2	Medical Equipment.
Medical Supplies	−0.4	−0.4	Medical Supplies.
Professional Liability Insurance	....	−0.4	Professional Liability Insurance.
Pharmaceuticals	7.8	....	Pharmaceuticals.
All Other Services	2.0	2.0	All Other Services.
Professional, Scientific & Technical Services	1.5	1.5	Professional, Scientific & Technical Services.
Administrative & Facility Services	2.4	2.4	Administrative & Facility Services.
Other Services	1.9	1.9	Other Services.
Capital	1.6	1.9	Capital.
Fixed Capital	2.1	2.1	Fixed Capital.
Moveable Capital	0.1	0.1	Moveable Capital.

For CY 2017, the proposed 2013-based FQHC market basket update (1.7 percent) is 0.4 percent higher than the 2006-based MEI (1.3 percent). The 0.4 percentage point difference stems mostly from the inclusion of pharmaceuticals in the proposed FQHC market basket. Prices for pharmaceuticals are projected to grow 7.8 percent, faster than the other components in the market basket. This cost category and associated price pressures are not included in the MEI.

We propose to update the FQHC PPS base payment rate by 1.7 percent for CY 2017 based on the proposed 2013-based FQHC market basket. The proposed FQHC market basket would more accurately reflect the actual costs and scope of services that FQHCs furnish compared to the 2006-based MEI. We invite public comment on all aspects of the FQHC market basket proposals.

C. Appropriate Use Criteria for Advanced Diagnostic Imaging Services

Section 218(b) of the PAMA amended Title XVIII of the Act to add section 1834(q) of the Act directing us to establish a program to promote the use of appropriate use criteria (AUC) for advanced diagnostic imaging services. The CY 2016 PFS final rule with comment period addressed the initial component of the new Medicare AUC program, specifying applicable AUC. In that rule we established evidence-based process and transparency requirements for the development of AUC, defined provider-led entities (PLEs) and established the process by which PLEs may become qualified to develop, modify or endorse AUC. The first list of qualified PLEs are expected to be posted on the CMS Web site by the end of June 2016 at which time their AUC libraries will be considered to be specified AUC for purposes of section 1834(q)(2)(A) of the Act.

This rule proposes requirements and processes for specification of qualified clinical decision support mechanisms (CDSMs) under the Medicare AUC program; the initial list of priority clinical areas; and exceptions to the requirement that ordering professionals consult specified applicable AUC when ordering applicable imaging services.

1. Background

AUC present information in a manner that links: A specific clinical condition or presentation; one or more services; and, an assessment of the appropriateness of the service(s). For purposes of this program, AUC are a set or library of individual appropriate use criteria. Each individual criterion is an evidence-based guideline for a particular clinical scenario. Each scenario in turn starts with a patient's presenting symptoms and/or condition. Evidence-based AUC for imaging can assist clinicians in selecting the imaging study that is most likely to improve health outcomes for patients based on their individual clinical presentation.

AUC need to be integrated as seamlessly as possible into the clinical workflow. CDSMs are the electronic portals through which clinicians would access the AUC during the patient workup. While CDSMs can be standalone applications that require direct entry of patient information, they may be more effective when they automatically incorporate information such as specific patient characteristics, laboratory results, and lists of co-morbid diseases from Electronic Health Records (EHRs) and other sources. Ideally, practitioners would interact directly with the CDSM through their primary user interface, thus minimizing interruption to the clinical workflow.

Consistent with definitions of CDSM by the Agency for Healthcare Research and Quality (AHRQ) (*http://www.ahrq.gov/professionals/prevention-chronic-care/decision/clinical/index.html*), and the Office of the National Coordinator for Health Information Technology (ONC) (*https://www.healthit.gov/policy-researchers-implementers/clinical-decision-support-cds*), within Health IT applications, a CDSM is a functionality that provides persons involved in care processes with general and person-specific information, intelligently filtered and organized, at appropriate times, to enhance health and health care.

2. Previous CDSM Experience

In the CY 2016 PFS final rule with comment period, we included a discussion of the Medicare Imaging Demonstration (MID), which was required by section 135(b) of the MIPPA, in addition to independent experiences of implementing AUC by several healthcare systems and academic medical centers. Two key aspects of that discussion remain relevant to the CDSM component of this program. First, AUC, and the CDSMs through which clinicians access AUC, must be integrated into the clinical workflow and facilitate, not obstruct, evidence-based care delivery. For instance, a CDSM external to a provider's primary user interface could utilize an application program interface (API), a set of protocols and tools specifying how software components should interact, to pull relevant information into the decision support application. By adhering to common interoperability standards, such as the national standards advanced through certified health IT (see 2015 edition of criteria available in the **Federal Register** (80 FR 62601) and described in the Interoperability Standards Advisory at *https://www.healthit.gov/standards-advisory*), CDSMs could both ensure integration of patient-specific data from EHRs, and allow clinicians to optimize the time spent using the tool.

Second, the ideal AUC is an evidence-based guide that starts with a patient's specific clinical condition or presentation (symptoms) and assists the clinician in the overall patient workup, treatment, and follow-up. Imaging would appear as key nodes within the clinical management decision tree.

Other options outside of certified EHR technology exist to access AUC through CDSMs. Stand-alone, internet-based CDSMs are available and, although they will not interact with EHR data, can nonetheless search for and present AUC relevant to a patient's presenting symptoms or condition.

In communicating an appropriateness rating to the ordering practitioner, some CDSMs provide a scale with numeric ratings, some output a red, yellow, or green light while others provide a dichotomous yes or no. At this time, we do not believe there is one correct approach to communicating the level of appropriateness to the ordering professional. However, section 1834(q)(4)(B) of the Act requires that information be reported on the claim form as to whether the service would or would not adhere to the specified AUC consulted through a particular CDSM, or whether the AUC was not applicable to the service. We are requesting feedback from commenters regarding how appropriateness ratings provided by CDSMs could be interpreted and recorded for the purposes of this program.

There are different views about the comprehensiveness of AUC that should be accessible within CDSMs. Some stakeholders believe that the CDSM should contain as comprehensive a collection of AUC as possible, incorporating individual criteria from across all specified AUC libraries. The intent would be for ordering professionals to avoid the frustration, experienced and voiced by many clinicians participating in the MID, of spending time navigating the CDSM only to find that no criterion for their patient's specific clinical condition exists.

Other stakeholders believe, based on decades of experience rolling out AUC in the context of robust quality improvement programs that it is best to start with a CDSM that contains AUC for a few clinical areas where impact is large and evidence is strong. This would ensure that quality AUC are developed, and that clinicians and entire care teams could fully understand the AUC they are using, including when they do not apply to a particular patient.

As we stated in the CY 2016 PFS final rule with comment period, we believe there is merit to both approaches, and it has been suggested to us that the best approach may depend on the particular care setting. The second, ''focused'' approach may work better for a large health system that produces and uses its own AUC. The first, ''comprehensive'' approach may in turn work better for a smaller practice with broad image ordering patterns and fewer resources that wants to simply adopt and start using a complete AUC system developed elsewhere. We believe a successful program would allow flexibility, and under section 1834(q) of the Act, we foresee a number of sets of AUC developed by different PLEs, and an array of CDSMs from which clinicians may choose.

3. Priority Clinical Areas

We established in the CY 2016 PFS final rule with comment period that we would identify priority clinical areas through rulemaking, and that these may be used in the determination of outlier ordering professionals (a future phase of the Medicare AUC program). The concept of priority clinical areas allows us to implement an AUC program that combines the focused and comprehensive approaches to implementation discussed above. Although potentially large volumes of AUC (as some PLEs have large libraries of AUC) would become specified across clinical conditions and advanced imaging technologies, we believe this rapid and comprehensive roll out of specified AUC should be balanced with a more focused approach when identifying outlier ordering professionals. We believe this will provide an opportunity for physicians and practitioners to become familiar with AUC in identified priority clinical areas prior to Medicare claims for those services being part of the input for calculating outlier ordering professionals.

As we describe earlier, CDSMs are the access point for ordering professionals to consult AUC. We believe the combination of the comprehensive and focused approaches should be applied to CDSM requirements as we consider a minimum floor of AUC that must be made available to ordering professionals through qualified CDSMs. AUC that reasonably address the entire clinical scope of priority clinical areas could establish a minimum floor of AUC to be included in qualified CDSMs, and the number of priority clinical areas could be expanded through annual rulemaking and in consultation with physicians and other stakeholders. This allows priority clinical areas to roll out judiciously, and build over time.

4. Statutory Authority

Section 218(b) of the PAMA added a new section 1834(q) of the Act entitled, ''Recognizing Appropriate Use Criteria for Certain Imaging Services,'' which directs the Secretary to establish a new program to promote the use of AUC. Section 1834(q)(3)(A) of the Act requires the Secretary to specify qualified CDSMs that could be used by ordering professionals to consult with specified applicable AUC for applicable imaging services.

5. Discussion of Statutory Requirements

There are four major components of the AUC program under section 1834(q) of the Act, each with its own implementation date: (1) Establishment of AUC by November 15, 2015 (section 1834(q)(2)); (2) identification of mechanisms for consultation with AUC by April 1, 2016 (section 1834(q)(3)); (3) AUC consultation by ordering professionals and reporting on AUC consultation by furnishing professionals by January 1, 2017 (section 1834(q)(4)); and (4) annual identification of outlier ordering professionals for services furnished after January 1, 2017 (section 1834(q)(5)). As we will discuss later in this preamble, we did not identify mechanisms for consultation by April 1, 2016 and will not have specified or published the list of qualified CDSMs by January 1, 2017; therefore, ordering professionals will not be required to consult CDSMs, and furnishing professionals will not be able to report information on the consultation, by this date.

a. Establishment of AUC

In the CY 2016 PFS final rule with comment period, we addressed the first component under section 1834(q)(2) of the Act—the requirements and process for establishment and specification of applicable AUC, along with relevant aspects of the definitions under section 1834(q)(1) of the Act. This included defining the term PLE and finalizing requirements for the rigorous, evidence-based process by which a PLE would develop AUC, upon which qualification is based, as provided in section 1834(q)(2)(B) of the Act and in the CY 2016 PFS final rule with comment period. Using this process, once a PLE is qualified by CMS, the AUC that are developed, modified or endorsed by the qualified PLE are considered to be specified applicable AUC under section 1834(q)(2)(A) of the Act. We defined the term PLE to include national professional medical societies, health systems, hospitals, clinical practices and collaborations of such entities such as the High Value Healthcare Collaborative or the National Comprehensive Cancer Network. Qualified PLEs may collaborate with third parties that they believe add value to their development of AUC, provided such collaboration is transparent. We expect qualified PLEs to have sufficient infrastructure, resources, and the relevant experience to develop and maintain AUC according to the rigorous, transparent, and evidence-based processes detailed in the CY 2016 PFS final rule with comment period.

A timeline and process was established for PLEs to apply to become qualified with the first list of qualified PLEs expected to be published at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Appropriate-Use-Criteria-Program/index.html* by June 30, 2016.

b. Mechanism for AUC Consultation

The second major component of the Medicare AUC program is the specification of qualified CDSMs that could be used by ordering professionals for consultation with specified applicable AUC under section 1834(q)(3) of the Act. We envision a CDSM as an interactive tool that communicates AUC information to the user. Information regarding the clinical presentation of the patient would be incorporated into the CDSM from another health IT system or through data entry by the ordering professional. At a minimum, the tool would provide immediate feedback to the ordering professional on the appropriateness of one or more imaging services. Ideally, CDSMs would be integrated within or seamlessly interoperable with existing health IT systems and would automatically receive patient data from the EHR or through an API or other connection. Such integration would minimize burden on practitioners and avoid duplicate documentation. Also useful to clinicians would be the ability to switch between CDSMs that can interoperate based on common standards.

Section 1834(q)(3)(A) of the Act states that the Secretary must specify qualified CDSMs in consultation with physicians, practitioners, health care technology experts, and other stakeholders. This paragraph authorizes the Secretary to specify mechanisms that could include: CDS modules within certified EHR technology; private sector CDSMs that are independent of certified EHR technology; and a CDSM established by the Secretary. The Secretary does not propose to establish a CDSM at this time.

All CDSMs must meet the requirements under section 1834(q)(3)(B) of the Act, which specifies that a mechanism must: Make available to the ordering professional applicable AUC and the documentation supporting the appropriateness of the applicable imaging service that is ordered; where there is more than one applicable appropriate use criterion specified for an applicable imaging service, indicate the criteria it uses for the service; determine the extent to which an applicable imaging service that is ordered is consistent with the applicable AUC; generate and provide to the ordering professional documentation to demonstrate that the qualified CDSM was consulted by the ordering professional; be updated on a timely basis to reflect revisions to the specification of applicable AUC; meet applicable privacy and security standards; and perform such other functions as specified by the Secretary (which may include a requirement to provide aggregate feedback to the ordering professional). Section 1834(q)(3)(C) of the Act specifies that the Secretary must publish an initial list of specified mechanisms no later than April 1, 2016, and that the Secretary must identify on an annual basis the list of specified qualified CDSMs.

As we explained in the CY 2016 PFS proposed and final rules with comment period, implementation of many aspects of the amendments made by section 218(b) of the PAMA requires consultation with physicians, practitioners, and other stakeholders, and notice and comment rulemaking. We continue to believe the PFS calendar year rulemaking process is the most appropriate and administratively feasible implementation vehicle. Given the timing of the PFS rulemaking process, we were not able to include proposals in the PFS proposed rule to begin implementation in the same year the PAMA was enacted, as we would have had to interpret and analyze the new statutory language, and develop proposed plans for implementation in under one month. As we did prior to the CY 2016 PFS proposed rule when we met extensively with stakeholders to gain insight and hear their comments and concerns about the AUC program, we have used the time prior to the CY 2017 PFS proposed rule to meet with many of the same stakeholders but also a new group of stakeholders specifically related to CDSMs. In addition, we are continuing our stepwise approach to implementing this AUC program. The first phase of the AUC program (specifying AUC including defining what AUC are and specifying the process for developing them) was accomplished through last year's CY 2016 PFS final rule with comment period. For this second phase, we will use this CY 2017 PFS rulemaking process as the vehicle to establish requirements for CDSMs, and the process to specify qualified CDSMs, in a transparent manner that allows for stakeholder and public involvement. Therefore, the final CDSM requirements and process for CDSMs to become qualified would be published in the CY 2017 PFS final rule with comment period on or about November 1, 2016.

c. AUC Consultation and Reporting

The third major component of the AUC program is in section 1834(q)(4) of the Act, Consultation with Applicable Appropriate Use Criteria. This section establishes, beginning January 1, 2017, the requirement for an ordering professional to consult with a qualified CDSM when ordering an applicable imaging service that would be furnished in an applicable setting and paid for under an applicable payment system; and for the furnishing professional to include on the Medicare claim information about the ordering professional's consultation with a qualified CDSM. The statute distinguishes between the ordering and furnishing professional, recognizing that the professional who orders an applicable imaging service is usually not the same professional who bills Medicare for that service when furnished. Section 1834(q)(4)(C) of the Act provides for certain exceptions to the AUC consultation and reporting requirements including in the case of certain emergency services, inpatient services paid under Medicare Part A, and ordering professionals who obtain an exception due to a significant hardship. Section 1834(q)(4)(D) of the Act specifies that the applicable payment systems for the AUC consultation and reporting requirements are the PFS, hospital outpatient prospective payment system, and the ambulatory surgical center payment systems.

Since a list of qualified CDSMs is not yet available and will not be available by January 1, 2017, we will not require ordering professionals to meet this requirement by that date.

d. Identification of Outliers

The fourth component of the AUC program is in section 1834(q)(5) of the Act, Identification of Outlier Ordering Professionals. The identification of outlier ordering professionals under this paragraph facilitates a prior authorization requirement for outlier professionals beginning January 1, 2020, as specified under section 1834(q)(6) of the Act. Although we are not proposing to implement these sections in the CY 2017 PFS proposed rule, we propose below a list of priority clinical areas which may serve as part of the basis for identifying outlier ordering professionals.

6. Proposals for Implementation

We propose to amend our regulations at § 414.94, "Appropriate Use Criteria for Certain Imaging Services."

a. Definitions

In § 414.94(b), we propose to codify and add language to clarify some of the definitions provided in section 1834(q) of the Act, as well as define terms that were not defined in statute but for which a definition would be helpful for program implementation. In this section, we provide a description of the terms we propose to codify to facilitate understanding and encourage public comment on the AUC program.

We propose to define CDSM under § 414.94(b) as an interactive, electronic tool for use by clinicians that communicates AUC information to the user and assists them in making the most appropriate treatment decision for a patient's specific clinical condition. A CDSM would incorporate specified applicable AUC sets from which an ordering professional could select. A CDSM may be a module within or available through certified EHR technology (as defined in section 1848(o)(4) of the Act) or private sector mechanisms independent from certified EHR technology. If within or available through certified EHR technology, a qualified CDSM would incorporate relevant patient-specific information into the assessment of the appropriateness of an applicable imaging service.

As prescribed in section 1834(q) of the Act and § 414.94(b) of our regulations, the Medicare AUC program imposes requirements only for applicable imaging services furnished in applicable settings. Further, as specified in section 1834(q)(4)(D) of the Act, we propose to amend our regulation at § 414.94(b) to state that the applicable payment systems for the Medicare AUC program are the PFS under section

1848(b) of the Act, the prospective payment system for hospital outpatient department services under section 1833(t) of the Act, and the ambulatory surgical center payment systems under section 1833(i) of the Act. Applicable payment systems are relevant to implementation of section 1834(q)(4)(B) of the Act, entitled "Reporting by Furnishing Professionals."

We remind readers that in PFS rulemaking for CY 2016 we defined applicable imaging service in § 414.94(b) as an advanced diagnostic imaging service as defined in 1834(e)(1)(B) of the Act for which the Secretary determines (i) One or more applicable appropriate use criteria apply; (ii) There are one or more qualified clinical decision support mechanisms listed; and (iii) One or more of such mechanisms is available free of charge.

b. Priority Clinical Areas

We propose to establish a new § 414.94(e)(5) to set forth the initial list of priority clinical areas.

To compile this proposed list we performed an analysis of Medicare claims data using the CMS Chronic Conditions Data Warehouse (CCW) as the primary data source. The CCW contains 100 percent of Medicare claims for beneficiaries who are enrolled in the fee-for-service (FFS) program. Data were derived from the CCW's 2014 Part B non-institutional claim line file, which includes Part B services furnished during CY 2014. This is the main file containing final action claims data for non-institutional health care providers, including physicians, physician assistants, clinical social workers, nurse practitioners, independent clinical laboratories, and freestanding ambulatory surgical centers. The Part B non-institutional claim line file contains the individual line level information from the claim and includes Healthcare Common Procedure Coding System (HCPCS) code(s), diagnosis code(s) using the International Classification of Diseases, Ninth Revision (ICD–9), service dates, and Medicare payment amount. A publicly available version of this dataset can be downloaded from the CMS Web site at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Appropriate-Use-Criteria-Program/index.html.* We encourage stakeholders to review this dataset as a source that may help inform public comments related to the proposed priority clinical areas.

In the CY 2016 PFS final rule with comment period, we stated that when identifying priority clinical areas we may consider factors such as incidence and prevalence of disease, the volume and variability of utilization of imaging services, the strength of evidence for their use, and applicability of the clinical area to the Medicare population and to a variety of care settings.

Using the 2014 Medicare claims data referenced above, we ranked ICD–9 codes by the frequency with which they were used as the primary indication for specific imaging procedures, which in turn were identified by the volume of individual Current Procedural Terminology (CPT) codes for which payments were made in 2014. We extracted the top 135 ICD–9 codes from this list and formed clinically-related categories. Next, we searched manually through an electronic list of all ICD–9 codes to find others that would plausibly fit into each clinical grouping. This process required subjective clinical judgment on whether a particular ICD–9 code should be included in a given clinical group. The top eight clinical groupings (by volume of procedures) are what we are proposing as the initial list of priority clinical areas. The eight clinical areas account for roughly 40 percent of part B advanced diagnostic imaging services paid for by Medicare in 2014. We are aware that some stakeholders have suggested beginning the AUC program with no more than five priority clinical areas while others have suggested a far greater number. We believe the proposed eight priority clinical areas strike a reasonable balance that allows us to focus on a significant range and volume of advanced diagnostic imaging services.

We also considered extracting pulmonary embolism as a separate priority clinical area from the chest pain grouping based on stakeholder consultation and feedback. However, we decided not to identify pulmonary embolism separately, but are asking for public comment on whether pulmonary embolism should be included as a stand-alone priority clinical area. Based on our consultations with physicians, practitioners and other stakeholders, as required by section 218(b) of the PAMA, we attempted to be inclusive when grouping ICD–9 codes into cohesive clinical areas. As an example of how we derived the priority clinical area for low back pain, we grouped together 10 ICD–9 codes, incorporating six from the top 135 and four from the manual search of all ICD–9 codes. Included in this grouping are the ICD–9 codes for displacement of lumbar intervertebral disc without myelopathy (722.10), degeneration of lumbar of lumbosacral intervertebral disc (722.52), intervertebral disc disorder with myelopathy lumbar region (722.73), post-laminectomy syndrome of lumbar region (722.83), lumbago (724.2), sciatica (724.3), thoracic or lumbosacral neuritis or radiculitis unspecified (724.4), spinal stenosis, lumbar region, without neurogenic claudication (724.02), lumbosacral spondylosis without myelopathy (721.3), and spondylosis with myelopathy lumbar region (721.42) which resulted in 1,883,617 services. To see all of the priority clinical area groupings of diagnosis codes, a table is available on the CMS Web site at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Appropriate-Use-Criteria-Program/index.html.*

Using the above methodology, we developed and are proposing eight priority clinical areas. These reflect both the significance and the high prevalence of some of the most disruptive diseases in the Medicare population.

TABLE 34—PROPOSED PRIORITY CLINICAL AREAS WITH CORRESPONDING CLAIMS DATA

Proposed priority clinical area	Total services	% Total services[1]	Total payments	% Total payments/1
Chest Pain (includes angina, suspected myocardial infarction, and suspected pulmonary embolism)	4,435,240.00	12	$ 470,395,545	14
Abdominal Pain (any locations and flank pain)	2,973,331.00	8	235,424,592	7
Headache, traumatic and non-traumatic	2,107,868.00	6	89,382,087	3
Low back pain	1,883,617.00	5	180,063,352	5
Suspected stroke	1,810,514.00	5	119,574,141	4
Altered mental status	1,782,794.00	5	83,296,007	3
Cancer of the lung (primary or metastatic, suspected or diagnosed)	1,114,303.00	3	154,872,814	5

TABLE 34—PROPOSED PRIORITY CLINICAL AREAS WITH CORRESPONDING CLAIMS DATA—Continued

Proposed priority clinical area	Total services	% Total services [1]	Total payments	% Total payments/1
Cervical or neck pain	1,045,381.00	3	83,899,299	3

[1] Percentage of 2014 Part B non-institutional claim line file for advanced imaging services from Medicare claims for beneficiaries who are enrolled in the fee-for-service (FFS) program (source: CMS Chronic Conditions Data Warehouse).

CMS also engaged the CMS Alliance to Modernize Healthcare (CAMH) Federally Funded Research and Development Center (FFRDC), the MITRE Corporation (MITRE), to begin developing efficient and effective processes for managing current and future health technology assessments. MITRE generated an independent report that presents a summary of findings from claims data from the Medicare population and their utilization of advanced imaging procedures. Coupled with our internal analysis, this report has assisted in identification of proposed priority clinical areas for the Medicare AUC program for advanced diagnostic imaging services. Analysis and methods for this report are available at *https://www.mitre.org/publications/technical-papers/claims-data-analysis-to-define-priority-clinical-areas-for-advanced.*

While this year we are proposing priority clinical areas based on an analysis of claims data alone, we may use a different approach in future rulemaking cycles. As we provided in § 414.94(e) of our regulations, we may consider factors other than volume when proposing priority clinical areas including incidence and prevalence of disease, variability of use of particular imaging services, strength of evidence supporting particular imaging services and the applicability of a clinical area to a variety of care settings and to the Medicare population.

We encourage public comments on this proposed initial list of priority clinical areas, including recommendations for other clinical areas that we should include among our list of priority clinical areas. In particular, we are interested in comments on the above methodology or alternate options; whether the proposed priority clinical areas are appropriate including information on the extent to which these proposed priority clinical areas may be represented by clinical guidelines or AUC in the future. Furthermore, we are interested in public comments, supported by published information, with respect to varying levels of evidence that exist across as well as within priority clinical areas.

c. CDSM Qualifications and Requirements

We are proposing to add a new § 414.94(g)(1) to our regulations to establish requirements for qualified CDSMs. Section 1834(q)(3)(A)(iii) of the Act provides relative flexibility for qualified CDSMs, and states that they may include mechanisms that are within certified EHR technology, private sector mechanisms that are independent from certified EHR technology or mechanisms that are established by the Secretary.

We believe that, at least initially, it is in the best interest of the program to establish CDSM requirements that are not prescriptive about specific IT standards. Rather, we are proposing an approach that focuses on the functionality and capabilities of qualified CDSMs. The CDSM, EHR and health IT environments are constantly changing and improving and we want to allow room for growth and innovation. However, in the future, as more stakeholders and other entities including the ONC, AHRQ, and relevant standards development organizations come to consensus regarding standards for CDSMs, then we may consider pointing to such standards as a requirement for qualified CDSMs under this program. We believe standards would make it possible to achieve interoperability, allowing any CDSM to incorporate any standardized AUC and for sets of AUC to be easily interchangeable among various CDSMs. We will continue to work with the ONC and AHRQ to facilitate movement in this direction.

Recent work under the federally-sponsored Clinical Quality Framework (CQF) initiative has successfully developed an integrated approach that harmonizes standards for electronic clinical quality measurement with those that enable shareable clinical decision support artifacts (for example, AUC). The CQF initiative is working to support semantically interoperable data exchange for (1) sending patient data to a service for clinical decision support guidance and receiving clinical decision support guidance or quality measurement results in return, and (2) enabling a system to consume and internally execute decision support artifacts. As this standard is considered sufficiently mature for widespread adoption, the ONC may consider it for use in future editions of certification criteria for health IT. While the current regulation requires no specific standard, the CMS and ONC are supportive of this approach and additional information can be found at *http://hl7-fhir.github.io/cqif/cqif.html.*

Under § 414.94(g)(1), we propose to codify in regulations the seven requirements for qualified CDSMs set forth in section 1834(q)(3)(B)(ii) of the Act. The Act requires qualified CDSMs to make available to the ordering professional specified applicable AUC and the supporting documentation for the applicable imaging service ordered. We do not interpret this requirement to mean that every qualified CDSM must make available every specified applicable AUC. In the CY 2016 PFS final rule with comment period we allowed for the approval of massive libraries of AUC (resulting from approvals for qualified PLEs with comprehensive and extensive libraries), yet we expressed our intention to establish priority clinical areas. While there is a statutory requirement to consult AUC for each applicable imaging service, we recognize that ordering professionals may choose to thoroughly improve their understanding of, and focus their internal quality improvement (QI) programs on, those priority clinical areas; and these areas will in turn serve as the basis for future outlier calculations.

Consistent with that approach, we propose to add a requirement in § 414.94(g)(1)(iii) that qualified CDSMs must make available to ordering professionals, at a minimum, specified applicable AUC that reasonably encompass the entire clinical scope of all priority clinical areas. We encourage and expect some CDSMs, based on the needs of the professionals they serve, will choose to include a far more comprehensive set of AUC going above and beyond the minimum set as we understand many ordering professionals want such comprehensive access to AUC. When this Medicare AUC program is fully implemented, all ordering professionals must consult specified applicable AUC through a qualified

CDSM for every applicable imaging service that would be furnished in an applicable setting and paid for under an applicable payment system in order for payment to be made for the service. However, when identifying the outlier ordering professionals who will be subject to prior authorization beginning in 2020, we anticipate focusing on consultation with specified applicable AUC within priority clinical areas rather than the universe of specified applicable AUC. The concept of priority clinical areas will allow us to implement an AUC program that combines two approaches to implementation allowing clinicians flexibility to either engage with a rapid rollout of comprehensive specified applicable AUC or adopt a focused approach to consulting AUC. Thus, they can choose their approach and select a CDSM and AUC set(s) that fit their needs and preferences, while being sure that each qualified CDSM will include AUC that address all priority clinical areas.

We further propose to add a requirement in § 414.94(g)(1)(iv) of our regulations that qualified CDSMs must be able to incorporate specified applicable AUC from more than one qualified PLE. We believe this approach ensures that CDSMs can expand the AUC libraries they can provide access to in order to represent AUC across all priority clinical areas (consistent with the requirements under proposed § 414.94(g)(1)(iii)). We do not necessarily expect that a single qualified PLE will develop AUC addressing every priority clinical area domain, especially since we believe that over time and through future rulemaking, the list of priority clinical areas will expand and cross additional clinical domains. Ensuring that qualified CDSMs are not limited in their technology to incorporating AUC from only one qualified PLE will help to ensure that ordering professionals will not be in a position of consulting a CDSM that cannot offer them access to AUC that address all priority clinical areas. As stakeholders continue to advance CDSM technology, we look forward to standards being developed and widely accepted so that AUC are incorporated in a standardized format across CDSM platforms. Increasing standardization in this area will move the industry closer to the goal of interoperability across CDSMs and EHRs.

We also propose to add a requirement in § 414.94(g)(1)(i) that specified applicable AUC and related documentation supporting the appropriateness of the applicable imaging service ordered must be made available within the qualified CDSM. For example, the ordering professional would have immediate access to the full appropriate use criterion, citations supporting the criterion and a summary of key evidence supporting the criterion.

We propose to add a requirement in § 414.94(g)(1)(ii), consistent with section 1834(q)(3)(B)(ii)(II) of the Act, that the qualified CDSM must clearly identify the appropriate use criterion consulted if the tool makes available more than one criterion relevant to a consultation for a patient's specific clinical scenario. We believe this is important since CDSMs that choose to incorporate a comprehensive AUC library may be offering the ordering professional access to AUC from multiple qualified PLEs. In such scenarios, it is important that the ordering professional knows which appropriate use criterion is being consulted and have the option to choose one over the other if more than one criterion applies to the scenario.

We propose to add a requirement in § 414.94(g)(1)(v), consistent with section 1834(q)(3)(B)(ii)(III) of the Act, that the qualified CDSM must provide to the ordering professional a determination, for each consultation, of the extent to which an applicable imaging service is consistent with specified applicable AUC or a determination of "not applicable" when the mechanism does not contain a criterion that would apply to the consultation. This determination would communicate the appropriateness of the applicable imaging service to the ordering professional. In addition to this determination, we also propose that the CDSM provide the ordering professional with a determination of "not applicable" when the mechanism does not contain an appropriate use criterion applicable to that patient's specific clinical scenario.

We propose to add a requirement in § 414.94(g)(1)(vi), consistent with section 1834(q)(3)(B)(ii)(IV) of the Act, that the qualified CDSM must generate and provide to the ordering professional certification or documentation that documents which qualified CDSM was consulted, the name and NPI of the ordering professional that consulted the CDSM and whether the service ordered would adhere to applicable AUC, whether the service ordered would not adhere to such criteria, or whether such criteria was not applicable for the service ordered. We propose to require under § 414.94(g)(1)(vi)(A) that this certification or documentation must be issued each time an ordering professional consults the qualified CDSM. Since Medicare claims will be filed only for services that are rendered to beneficiaries, we will not see CDSM consultation information on the claim form specific to imaging services that are not ordered. We believe that for the CDSM to be able to provide meaningful feedback to ordering professionals, information regarding consultations that do not result in imaging is just as important as information on consultations that do result in an order for advanced imaging.

Thus, we propose to require under § 414.94(g)(1)(vi)(B) that the documentation or certification provided by the qualified CDSM must include a unique consultation identifier. This would be a unique code issued by the CDSM that is specific to each consultation by an ordering professional. This type of unique code may serve as a platform for future collaboration and aggregation of consultation data across CDSMs. In addition, at some point in the future, this unique code may assist in more seamlessly bringing Medicare data together with CDSM clinical data to maximize quality improvement in clinical practices and to iteratively improve the AUC itself.

We propose in § 414.94(g)(1)(vii), consistent with section 1834(q)(3)(B)(ii)(V) of the Act, that the specified applicable AUC content within qualified CDSMs be updated at least every 12 months to reflect revisions or updates made by qualified PLEs to their AUC sets or to an individual appropriate use criterion. We propose 12 months as the maximum acceptable delay for updating content. We believe that in most cases it will be possible to update AUC content more frequently than every 12 months, particularly for cloud-based CDSMs. We further propose in § 414.94(g)(1)(vii)(A) that qualified CDSMs have a protocol in place to more expeditiously remove AUC that are determined by the qualified PLE to be potentially dangerous to patients and/or harmful if followed.

In addition, we propose in § 414.94(g)(1)(vii)(B) that qualified CDSMs must make available for consultation specified applicable AUC that address any new priority clinical areas within 12 months of the priority clinical area being finalized by CMS. We believe this would allow the CDSM sufficient time to incorporate the AUC into the CDSM. Thus, any new priority clinical areas finalized, for example, in the CY 2018 PFS final rule with comment period that would be effective January 1, 2018, would need to be incorporated into a qualified CDSM by January 1, 2019. To accommodate this time frame, we would accept a not applicable determination from a CDSM for a consultation on a priority clinical area for dates of service through the 12-month period that ends, in this example, on January 1, 2019. We note that all qualified CDSMs that are approved by June 30, 2017 should be capable of supporting AUC for all priority clinical areas that are finalized in the CY 2017 PFS final rule with comment period.

We propose to add a requirement in § 414.94(g)(1)(viii), consistent with section 1834(q)(3)(B)(ii)(VI) of the Act, that the qualified mechanism must meet privacy and security standards under applicable provisions of law. Potentially applicable laws may include the HIPAA Privacy and Security rules.

We propose to add a requirement in § 414.94(g)(1)(ix), consistent with section 1834(q)(3)(B)(ii)(VII) of the Act, that qualified CDSMs must provide ordering professionals aggregate feedback in the form of an electronic report on an annual basis (at minimum) regarding their consultations with specified applicable AUC. Our intent is to require records to be retained in a manner consistent with the HIPAA Security Rule. To provide such feedback, and to make detailed consultation information available to ordering professionals, furnishing professionals (when they have authorized access to the CDSM), auditors and CMS, we propose in § 414.94(g)(1)(x) that a qualified CDSM must maintain electronic storage of clinical, administrative and demographic information of each unique consult for a minimum of 6 years. We believe CDSMs could fulfill this requirement in a number of ways, including involving a third party in the storage of information as well as for providing feedback to ordering professionals. We recognize that these requirements represent a minimum floor that clinicians may choose to expand upon in their local QI programs.

In the event requirements under § 414.94(g)(1) are modified through rulemaking during the course of a qualified CDSM's 5-year approval cycle, we propose in § 414.94(g)(1)(xi) that the CDSM would be required to comply with the modification(s) within 12 months of the effective date of the modification.

d. Process for CDSMs To Become Qualified and Determination of Non-Adherence

We propose that CDSMs must apply to CMS to be specified as a qualified CDSM. We propose that CDSM developers who believe their mechanisms meet the regulatory requirements must submit an application to us that documents adherence to each of the requirements to be a qualified CDSM.

We propose to require in § 414.94(g)(2) that CDSM developers must submit applications to CMS for review that document adherence to each of the CDSM requirements. Applications to be specified as a qualified CDSM must be submitted by January 1 of a year in order to be reviewed within that year's review cycle. For example, the first applications would be accepted from the date of publication of the PFS final rule until January 1, 2017. A determination on whether the applicants are qualified would be made by June 30, 2017. Applications must be submitted electronically to *ImagingAUC@cms.hhs.gov*. This process and timeline mirror the qualified PLE application and approval process and timeline. As we did for qualified PLEs, we will post a list of all applicants that we determine to be qualified CDSMs to our Web site at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Appropriate-Use-Criteria-Program/index.html* by June 30. We propose that all qualified CDSMs must reapply every 5 years and their applications must be received by January 1 during the 5th year that they are qualified CDSMs. It is important to note that, as with PLE applications, the application for qualified CDSMs is not a CMS form; rather it is created by the applicant. A CDSM that is specified as qualified for the first 5-year cycle beginning on July 1, 2017 would be required to submit an application for requalification by January 1, 2022. A determination would be made by June 30, 2022, and, if approved, the second 5-year cycle would begin on July 1, 2022.

An example of our proposed timeline for applications and the approval cycle is as follows:

- Year 1 = July 2017 to June 2018.
- Year 2 = July 2018 to June 2019.
- Year 3 = July 2019 to June 2020.
- Year 4 = July 2020 to June 2021.
- Year 5 = July 2021 to June 2022 (reapplication is due by January 1, 2022).

We believe it is important for us to have the ability to remove from the list of specified qualified CDSMs a CDSM that we determine fails to adhere to any of the qualification requirements, including removal outside of the proposed 5-year cycle. We propose to state under § 414.94(h) that, at any time, we may remove from the list of qualified CDSMs a CDSM that fails to meet the criteria to be a qualified CDSM or consider this information during the requalification process. Such determinations may be based on public comment or our own review and we may consult with the National Coordinator for Health Information Technology or her designee to assess whether a qualified CDSM continues to adhere to requirements.

We invite comments on how we could streamline and strengthen the approval process for CDSMs in future program years. For instance, CMS may consider a testing framework for CDSMs that would validate adherence to specific standards that enable seamless incorporation of AUC across CDSMs.

e. Consultation by Ordering Professional and Reporting by Furnishing Professional

Although we continue to aggressively move forward to implement this AUC program, ordering professionals will not be expected to consult qualified CDSMs by January 1, 2017. At the earliest, under this proposal, the first qualified CDSM(s) will be specified on June 30, 2017. We anticipate that some ordering professionals could be able to begin consulting AUC through qualified CDSMs very quickly as some may already be aligned with a qualified CDSM.

We anticipate that furnishing professionals may begin reporting as early as January 1, 2018. This reporting delay is necessary to allow time for ordering practitioners who are not already aligned with a qualified CDSM to research and evaluate the qualified CDSMs so they may make an informed decision. While there will be further rulemaking next year, we are announcing this date because the agency expects physicians and other stakeholders/regulated parties to begin preparing themselves to begin reporting on that date. We will adopt procedures for capturing this information on claims forms and the timing of the reporting requirement through PFS rulemaking for CY 2018.

As we expect to implement the AUC consultation and reporting requirements under section 1834(q)(4)(A) and (B) of the Act on January 1, 2018, we are interested in receiving feedback from the public to include a discussion of specific operational considerations that we should take into account and include in such rulemaking. For example, commenters could consider alternatives for reporting data on claims and for seeking exceptions, as discussed below. We also seek information on the barriers to implementation along this timeline that allows ordering and furnishing professionals to be prepared to consult AUC and report consultation information on the claims and whether separate rulemaking outside of the payment rule cycle would be preferred.

Under section 1834(q)(4)(B) of the Act, Medicare claims for applicable imaging services furnished in applicable settings can only be paid under the applicable payment systems if certain information is included on the claim including: Which qualified CDSM was consulted by the ordering professional for the service; whether the service, based on the CDSM consultation, adheres to specified applicable AUC, does not adhere to specified applicable AUC or whether no criteria in the CDSM were applicable to the patient's clinical scenario; and, the national provider identifier (NPI) of the ordering professional. This section further allows payment for these services only if the claim contains such information beginning January 1, 2017. To develop and operationalize a meaningful solution to collecting new AUC consultation-related information on the claims, we must diligently evaluate our options taking into account the vast number of claims impacted and the limitations of the legacy claims processing system. While we could have moved more quickly to establish some sort of AUC consultation indicator for Medicare claims, any such indicator would have been a relatively meaningless token. Additionally, in the case of advanced imaging services, related claims are already required to append certain HCPCS modifiers and G codes for purposes of proper payments. In the recent implementation of section 218(a) of the PAMA, we established a HCPCS modifier for CT services rendered on machines that do not meet an equipment standard. It is important that we understand and evaluate how the additional requirements for AUC reporting would impact the information that is already required for advanced imaging services. Moving too quickly to satisfy the reporting requirement could inadvertently result in technical and operational problems that could cause delays in payments.

Section 1834(q)(4)(C) of the Act includes exceptions that allow claims to be paid even though they do not include the information about AUC consultation by the ordering professional. We believe that, unless a statutory exception applies, an AUC consultation must take place for every order for an applicable imaging service furnished in an applicable setting and under an applicable payment system. We further believe that section 1834(q)(4)(B) of the Act accounts for the possibility that AUC may not be available in a particular qualified CDSM to address every applicable imaging service that might be ordered; and thus, the furnishing professional can meet the requirement to report information on the ordering professional's AUC consultation by indicating that AUC is not applicable to the service ordered.

We are considering the mechanisms for appending the AUC consultation information to various types of Medicare claims and expect to develop requirements for appending such information in the CY 2018 PFS rulemaking process. Stakeholders interested in sharing feedback related to reporting and claims processing are welcome to do so as part of the comment period for this proposed rule. We are particularly interested in receiving feedback on, for example, whether the information should be collected using HCPCS level II G codes or HCPCS modifiers. We will use this feedback to inform CY 2018 rulemaking.

f. Exceptions To Consulting and Reporting Requirements

Section 1834(q)(4)(C) of the Act provides for certain exceptions to the AUC consultation and reporting requirements under section 1834(q)(4)(B) of the Act. First, the statute provides for an exception under section 1834(q)(4)(C)(i) of the Act where an applicable imaging service is ordered for an individual with an emergency medical condition as defined in section 1867(e)(1) of the Act. We believe this exception is warranted because there can be situations in which a delay in action would jeopardize the health or safety of individuals. Though we believe they occur primarily in the emergency department, these emergent situations could potentially arise in other settings. Furthermore, we recognize that most encounters in an emergency department are not for an emergency medical condition as defined in section 1867(e)(1) of the Act.

We propose to provide for an exception to the AUC consultation and reporting requirements under § 414.94(i)(1) for an applicable imaging service ordered for an individual with an emergency medical condition as defined in section 1867(e)(1) of the Act. For example, if a patient, originally determined by the clinician to have an emergency medical condition prior to ordering an applicable imaging service, is later determined not to have had an emergency medical condition at that time, the relevant claims for applicable imaging services would still qualify for an exception. To meet the exception for an emergency medical condition as defined in section 1867(e)(1) of the Act, the clinician only needs to determine that the medical condition manifests itself by acute symptoms of sufficient severity (including severe pain) such that the absence of immediate medical attention could reasonably be expected to result in: Placing the health of the individual (or a woman's unborn child) in serious jeopardy; serious impairment to bodily functions; or serious dysfunction of any bodily organ or part. Orders for advanced imaging services for beneficiaries with an emergency medical condition as defined under section 1867(e)(1) of the Act are excepted from the requirement to consult AUC. We intend through the CY 2018 PFS proposed rule to propose more details around how this exception will be identified on the Medicare claim.

The second exception is under section 1834(q)(4)(ii) of the Act for applicable imaging services ordered for an inpatient and for which payment is made under Medicare Part A. We propose to codify this exception in new § 414.94(i)(2). While we are including this exception consistent with statute, we note that if payment is made under Medicare Part A, the service would not be paid under an applicable payment system, such that the AUC consultation and reporting requirements under § 414.94 would never apply.

The third exception is under section 1834(q)(4)(iii) of the Act for applicable imaging services ordered by an ordering professional who the Secretary determines, on a case-by-case basis and subject to annual renewal, that consultation with applicable AUC would result in a significant hardship, such as in the case of a professional practicing in a rural area without sufficient Internet access. We propose to codify this exception in new § 414.94(i)(3) by specifying that ordering professionals who are granted a significant hardship exception for purposes of the Medicare EHR Incentive Program payment adjustment under § 495.102(d)(4)(i), (ii), or (iii)(A)(B) of our regulations would also be granted a significant hardship exception for purposes of the AUC consultation requirement. We are proposing, to the extent technically feasible, that the year for which the eligible professional is excepted from the EHR Incentive Program payment adjustment is the same year that the ordering professional is excepted from the requirement to consult AUC through a qualified CDSM. We propose not to adopt the Meaningful Use significant hardship exception under § 495.102(d)(4)(iv)(C) as an exception for purposes of the AUC consultation requirement. Therefore, ordering professionals with a primary specialty of anesthesiology, radiology or pathology will not be categorically excepted from AUC consultation requirements.

We believe there is substantial overlap between the eligible professionals that would seek a hardship exception under the EHR Incentive Program and those ordering professionals that would seek a hardship exception under the AUC program and, as such, this proposal would be administratively efficient. Using an existing program is the most efficient and expeditious manner to implement the significant hardship exception under the Medicare AUC program. We also believe it is the only administratively feasible option for a national significant hardship identification process that can be implemented by January 1, 2018, though we intend to revisit this option for years after 2018 as the current EHR Incentive Program payment adjustment is set to expire after the 2018 payment year as the Merit-Based Incentive Payment System takes effect. In addition, below we discuss considerations for a supplemental process to account for hardships for ordering professionals that are not eligible to apply for a significant hardship under the EHR Incentive Program (for example, non-physician practitioners) and ordering professionals that incur a significant hardship outside of the EHR Incentive Program application deadline.

The criteria for significant hardships under the EHR Incentive Program relate to insufficient internet connectivity, practicing for less than 2 years, practicing at multiple locations with the inability to control the availability of Certified EHR Technology, lack of face-to-face interaction with patients or a primary specialty designation of anesthesiology, radiology or pathology. We believe that most of these criteria would be relevant to demonstrate a significant hardship for ordering professionals to consult AUC. Regarding hardship exceptions for certain specialty designations, based on Medicare claims data for advanced imaging services from the first 6 months of 2014, approximately 1.2 percent of those claims were for advanced imaging services that had been ordered by a professional with one of the three primary specialty designations. While their combined ordering volume is small, we do not believe that categorical exclusion of certain specialties of which the practitioner selected as their primary specialty designation for Medicare enrollment would necessarily be appropriate under the AUC program. Since eligible professionals in these three specialties are categorically excepted from the EHR Incentive Program payment adjustment, few of them would have applied for an exception on the other grounds. Therefore, we must consider another mechanism to evaluate whether ordering practitioners with these medical specialties experience a significant hardship for purposes of the AUC program.

We understand that there are differences between the purpose and timing of significant hardship exceptions for the EHR Incentive Program and the Medicare AUC program. Foremost, a significant hardship under the EHR Incentive Program is generally based on a hardship that occurred in a prior period, impacting meaningful EHR use that would affect payments in a subsequent calendar year. For example, a professional that submits an application in March 2017 and qualifies for the hardship exception under the EHR Incentive Program would be exempt from the EHR payment adjustment for calendar year 2018. Although significant hardship exceptions for the EHR payment adjustment year generally are based on the existence of a hardship in a prior period, we believe it would be appropriate for these professionals to also qualify for a significant hardship exception for purposes of the AUC consultation requirement during calendar year 2018. It is also our best, most efficient, administratively feasible means of determining significant hardships for ordering professionals for CY 2018.

We also recognize the possibility that an ordering professional could suffer a significant hardship during the AUC program year, and therefore, is immediately unable to consult AUC. In addition, while again we believe there is significant overlap, there may be circumstances where an ordering professional is not considered to be an eligible professional under the EHR Incentive Program (for example, an ordering professional that is not a physician). We are seeking feedback from commenters regarding processes that could be put in place to accommodate ordering professionals with primary specialties that categorically receive significant hardship exceptions under the EHR Incentive Program, real-time hardships that arise during a year, and ordering professionals that are not eligible to apply using the EHR Incentive Program significant hardship exception process and need to seek a significant hardship exception for the purposes of the AUC program. We believe this would involve only a small number of ordering professionals. To the extent technically feasible, some possibilities for implementing such hardship exceptions may include Medicare Administrative Contractors granting hardships on a case-by-case basis or establishing another mechanism to allow for self-attestation of a significant hardship for a defined period of time (for example, a calendar quarter or a calendar year). We intend to propose a process in the CY 2018 PFS proposed rule.

We invite the public to comment on our proposal for ordering professionals granted a hardship exception for the EHR Incentive Program for payment year 2018 to also be granted a hardship exception to the Medicare AUC program for those years. We propose that the year the practitioner is excepted from the EHR Incentive Program payment adjustment is the same year that the practitioner would be excepted from consulting AUC.

6. Summary

Section 1834(q) of the Act includes rapid timelines for establishing a Medicare AUC program for advanced diagnostic imaging services. The number of clinicians impacted by the scope of this program is massive as it will apply to every physician or other practitioner who orders or furnishes applicable imaging services. This crosses almost every medical specialty and could have a particular impact on primary care physicians since their scope of practice can be quite broad.

We continue to believe the best implementation approach is one that is diligent, maximizes the opportunity for public comment and stakeholder engagement, and allows for adequate advance notice to physicians and practitioners, beneficiaries, AUC developers, and CDSM developers. It is for these reasons we are proposing to continue a stepwise approach, adopted through notice and comment rulemaking. We propose this second component to the program to specify qualified CDSMs, identify the initial list of priority clinical areas, and establish requirements related to CDSMs, as well as consulting and reporting exceptions. However, we also recognize the importance of moving expeditiously to accomplish a fully implemented program. Under this proposal, the first list of qualified CDSMs will be posted no later than June 30, 2017, allowing ordering professionals to begin aligning themselves with a qualified CDSM. We anticipate that furnishing professionals could begin reporting AUC information starting as early as January 1, 2018, but will provide details in CY 2018 PFS rulemaking for how to report that information on claims.

In summary, we propose definitions of terms and processes necessary to implement the second component of the AUC program. We invite the public to submit comments on these proposals. We are particularly seeking comment on the proposed priority clinical areas and the requirements that must be met by CDSMs to become qualified. We believe the proposed requirements for qualified CDSMs will allow for flexibility so mechanisms can continue to reflect innovative concepts in decision support and develop customer-driven products to ultimately provide information to the ordering professional in such a manner that will maximize appropriate ordering of advanced diagnostic imaging while seamlessly integrating into workflow. As the stakeholders continue to move to a place of consensus-based standards deemed ready for deployment, we may become more prescriptive in future requirements for CDSMs. We also seek comment on the exceptions to the requirements to consult applicable AUC using CDSMs.

D. Reports of Payments or Other Transfers of Value to Covered Recipients: Solicitation of Public Comments

1. Background

In the February 8, 2013 **Federal Register** (78 FR 9458), we published the "Transparency Reports and Reporting of Physician Ownership or Investment Interests" final rule (Open Payments Final Rule) which implemented section 1128G of the Act, as added by section 6002 of the Affordable Care Act. Under section 1128G(a)(1) of the Act, manufacturers of covered drugs, devices, biologicals, and medical supplies (applicable manufacturers) are required to submit on an annual basis information about certain payments or other transfers of value made to physicians and teaching hospitals (collectively called covered recipients) during the course of the preceding calendar year. Section 1128G(a)(2) of the Act requires applicable manufacturers and applicable group purchasing organizations (GPOs) to disclose any ownership or investment interests in such entities held by physicians or their immediate family members, as well as information on any payments or other transfers of value provided to such physician owners or investors. The Open Payments program creates transparency around the nature and extent of relationships that exist between drug, device, biologicals and medical supply manufacturers, and physicians and teaching hospitals (covered recipients and physician owner or investors). The implementing regulations are at 42 CFR part 402, subpart A, and part 403, subpart I.

In addition to the Open Payments final rule, we issued final regulations in the CY 2015 PFS final rule with comment period (79 FR 67758) that revised the Open Payments regulations. Specifically, we: (1) Deleted of the definition of "covered device"; (2) removed the continuous medical education (CME) exclusion; (3) expanded the marketed name reporting requirements to biologicals and medical supplies; and (4) required stock, stock options, and any other ownership interests to be reported as distinct forms of payment.

Since the publication and implementation of the Open Payments Final Rule and the CY 2015 PFS, various stakeholders have provided feedback to us regarding aspects of the Open Payment program. We have identified areas in the rule that might benefit from revision. In order to consider the views of all stakeholders, we are soliciting comments to inform future rulemaking. We do not intend to finalize any requirements related to Open Payments directly as a result of this proposed rule; rather, we expect to conduct future rulemaking. We are particularly interested in receiving comments on the following:

- We would like to know if the nature of payment categories as listed at § 403.904(e)(2) are inclusive enough to facilitate reporting of all payments or transfers of value to covered recipient physicians and teaching hospitals. We also seek feedback on further categorization of reported research payments.
- Although there is a 5-year record retention requirement at § 403.912(e), our regulations are currently silent on how long applicable manufacturers and applicable GPOs remain obligated to report on past years of payments or ownership or investment interests. We are soliciting feedback on how many years an applicable manufacturer or applicable GPO should continue to monitor and report on past program years for Open Payments reporting purposes.
- We are continuing to refresh all years of program data in addition to newly submitted payment records. We are interested in receiving feedback on how many years of Open Payments data is relevant to our stakeholders to help us determine how many years to continue to publish and refresh annually on our Web site. In addition, we are looking for feedback on how many years may be useful or relevant to Open Payments data users as archive files available for download on our Web site.
- We are seeking feedback on a requirement for all applicable manufacturers and applicable GPOs as defined in § 403.902 to register each year, regardless of whether the entity will be reporting payments or other transfers of value, or ownership or investment interests for the program year. We also seek comment on requiring applicable manufacturers and applicable GPOs to include the reason for not reporting any payments or other transfers of value, or ownership or investment interests.
- We are constantly striving to ensure that all published Open Payments data is valid and reliable. As part of this effort we are seeking comment on a requirement for applicable manufacturers and applicable GPOs to pre-vet payment information with covered recipients and physicians owners or investors before reporting to the Open Payments system, which we understand is an increasingly common practice. Specifically, we would like feedback on pre-vetting based on threshold payment values or random samplings of covered recipients. We are also interested in hearing how applicable manufacturers and applicable GPOs are successfully pre-vetting payment or transfer of value records.
- We continue to receive feedback that the current definition of a covered recipient teaching hospital, as defined at § 403.902, makes reporting payments or transfers of value difficult for applicable manufacturers. Section 1128G of the Act is silent on the definition of a covered recipient teaching hospital. We are soliciting feedback on the specific hurdles that the current definition presents. Additionally we would like to receive proposed alternative operationally feasible definitions or definitional elements of a covered recipient teaching hospital.
- We have heard from stakeholders that verifying receipt of payments or transfers of value to teaching hospitals is a difficult process on the recipient end for a various number of reasons (such as size of hospitals, number of departments, etc.). Without context around a payment record, teaching hospitals have reported difficulties verifying payments attributed to them. This leads to payment disputes. We are seeking feedback on adding a new non-public data element to assist in review and affirmation of payment records. Some examples might be hospital contact name or department etc. Would a free form text field be preferable?

Should this field be mandatory to facilitate review of any attributed payments to a teaching hospital?

- Some reporting entities have expressed interest to upload data into the Open Payments system before the end of the calendar year for which the data is collected. We believe this may increase data validity and minimize disputes. We solicit feedback on the benefit for applicable manufacturers and applicable GPOs to report data to CMS early or ongoing throughout the year.
- We recognize that some entities may experience mergers, acquisitions, corporate organizations and reorganizations, and other structural corporate changes. We seek feedback on how we might change our reporting requirements to ensure that industry can properly, and easily, represent these changes while still monitoring for compliance with reporting requirements.
- We have received feedback from industry that there is confusion surrounding requirements for reporting ownership and investment interests. Keeping in mind that these reporting requirements are statutorily mandated, we solicit feedback on operationally feasible definitions regarding ownership or investment interests. Specifically, we would like feedback on the terms "value or interest" and "dollar amount invested." We also solicit comments on additional terms that may require further clarification to facilitate compliance with reporting requirements.
- We solicit ideas on how to define physician-owned distributors (PODs) for data reporting purposes, as well as what data elements PODs should be required to report. We also seek feedback on what portion of the reported data we should share on our Web site.
- From a data collection perspective, we welcome suggestions on ways to streamline or make the process more efficient, while facilitating our role in oversight, compliance, and enforcement.
- With respect to all solicitations, we are requesting an estimate of the time and cost burden associated with reporting for purposes of compliance with the Paperwork Reduction Act.

E. Release of Part C Medicare Advantage Bid Pricing Data and Part C and Part D Medical Loss Ratio (MLR) Data

1. Background

As part of the annual bidding process required under section 1854(a) of the Act, Medicare Advantage organizations (MAOs) submit bids for each plan they wish to offer in the upcoming contract year (calendar year). We refer to each of these bids as a Medicare Advantage (MA) plan bid. As required by sections 1857(e)(4) and 1860D–12(b)(3)(D) of the Act, data supporting medical loss ratios (MLR) are submitted annually to us by MAOs and Part D sponsors, respectively. Using this authority, we codified the MLR submission requirement in the MLR final rule for Part C and Part D published in the **Federal Register** (78 FR 31284) on May 23, 2013.

We are proposing to release to the public MA bid pricing data and Part C and Part D MLR data on a specific schedule and subject to specified exclusions. We propose to add contract terms and expand the basis and scope of our regulations on MA bidding and Part C and Part D MLR submission to incorporate section 1106(a) of the Act (42 U.S.C. 1306(a)), which authorizes disclosure of information filed with this agency in accordance with regulations adopted by the agency. (*See Parkridge Hospital, Inc.* v. *Califano,* 625 F.2d 719, 724–25 (6th Cir. 1980). A substantive regulation issued following rulemaking provides the legal authorization for government officials to disclose commercial information that would otherwise be required to be kept confidential in accordance with 18 U.S.C. 1905. *See Chrysler Corp.* v. *Brown,* 441 U.S. 281, 306–08 (1979). We note as well that under 45 CFR 401.105(a),[6] we have adopted a regulation that permits publication and release of data that would not be exempt from disclosure under FOIA or prohibited from disclosure under other law, even if a request has not been submitted. We further note that because we collect Part D MLR information under section 1860D–12(b)(3)(D) of the Act, we have the authority to use such information for purposes of improving public health through research on the utilization, safety, effectiveness, quality and efficiency of health care services. We propose to adopt a regulation that clearly identifies the categories of data from submitted bids and reports of medical loss ratios that will be released so as to avoid repeating FOIA analyses and reviews of each request, to standardize the disclosure and the procedures for disclosure, and in the interest of furthering goals related to the MA and Part D programs.

The purposes underlying these proposed data releases include allowing public evaluation of the MA and Part D programs encouraging research into these programs and better ways to provide health care, and reporting to the public regarding federal expenditures and other statistics involving these programs. In particular, we believe that facilitating public research using this bid pricing data could lead to better understanding of the costs and utilization trends in MA and support future policymaking for the MA program. For example, MA bid pricing data (which contains actual and projected cost figures) could be used to understand patterns of health care utilization such as how projected and actual costs may differ across geographic areas and different beneficiary populations. Release of MLR data from the MA and Part D programs could lead to research into how managed care in the Medicare population differs from and is similar to managed care in other populations (such as the individual and group markets) where MLR data is also released publicly; such research could inform future administration of these programs. Further, we believe that making certain MA bid pricing data and Part C and Part D MLR data available publicly aligns with Presidential initiatives to improve management and transparency of federal information. The President's January 21, 2009, *Memorandum on Transparency and Open Government* (74 FR 4685) instructed federal agencies to take specific actions to implement increased data transparency and access to federal datasets. Subsequent Presidential memoranda (including the May 23, 2012 memorandum *Building a 21st Century Digital Government* and May 9, 2013 memorandum *Making Open and Machine Readable the New Default for Government Information*) further stated the policy initiative to increase open access to and interoperability among such government data sets. These memoranda demonstrate a commitment to making information about government activities and government spending available to the public and using the internet as a means of public disclosure in order to eliminate as many barriers as possible to public access to such information. Our proposal would promote accountability in the MA and Part D programs, by making MLR information publicly available for use by beneficiaries who are making enrollment choices and by allowing the public to see whether and how privately-operated MA and Part D plans administer Medicare—and supplemental—benefits in an effective and efficient manner. Disclosing MA pricing data would provide the public with insight as to how public dollars are spent in this aspect of the Medicare program. Further, we have received requests under FOIA for data of the type of the pricing data we propose to release here and we anticipate that, as the MLR Reports from MA and Part D plans are submitted, we will receive requests for those reports and that data.

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[6] The regulation, which implements 42 U.S.C. 1306(a), provides that the Freedom of Information Act rules shall be applied to every proposed disclosure of information. If, considering the circumstances of the disclosure, the information would be made available in accordance with the Freedom of Information Act rules, then the information may be disclosed regardless of whether the requester or beneficiary of the information has a statutory right to request the information under the Freedom of Information Act, 5 U.S.C. 552, or whether a request has been made.

These interests, however, must also be balanced with the need to protect the privacy of individuals, the confidentiality of information about Medicare beneficiaries, and the proprietary interests of the MA and Part D plans that submit the information. While transparency in governmental activities and spending is important, we recognize that some of the information we collect in the form of MA bid pricing submissions and Part C and Part D MLR reports should not be publicly disclosed. We believe that our proposal balances these various interests and goals, both in carving out from the planned and authorized releases certain specific data, and (in the case of the MA bid pricing data) in delaying the release past the point of the commercial usefulness of the data.

We are seeking to balance protection of the proprietary interests of MAOs and Part D sponsors with the need to effectively and transparently administer federal health care programs and to encourage research into better ways to provide health care. Further, we believe that adopting a fixed schedule for release of this information and standardizing releases of this data through this rule, will reduce the burdens on the public, CMS, and the submitters of the data that are associated with individual requests for information. Proposing a rule for these releases provides the opportunity for a fulsome and public dialogue that is not always the case with individual requests for information. We encourage commenters to identify and explain additional uses of the information we propose here to release and to suggest additional protections from release if commenters disagree with how we have balanced the competing interests. We hope to receive comments from all viewpoints to ensure that the lines for releasing and protecting information are appropriately drawn.

2. MA Bid Submission and Pricing Data

We make monthly prospective payments to MAOs for providing Part C coverage to Medicare beneficiaries enrolled in their MA plans. As mandated in section 1854 of the Act, amended by Title II of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173), our payments to MAOs for their MA plan enrollees are based on bids that MAOs must submit to us no later than the first Monday in June for the upcoming contract year. Each MA plan bid is an estimate of the plan's revenue requirement to cover plan benefits for a projected population. The monthly aggregate bid amount for an MA plan is composed of estimated benefit expenses (direct medical expenses), non-benefit expenses (administrative expenses), and a gain/loss margin (profit) for coverage of original Medicare benefits, Part C supplemental benefits (if any), and Part D benefits (if any). We are not proposing to release Part D bid pricing data in this rule. Also, cost plans operated under section 1876 and section 1833 of the Act, Program for All Inclusive Care for the Elderly (PACE) organizations, and Medicare-Medicaid demonstration plans operated under the Financial Alignment Initiative (*https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/FinancialModelstoSupportStatesEffortsinCareCoordination.html*) do not submit Part C bids to us so pricing data relating to those plans is not part of this proposed rule.

Section 1854(a) of the Act requires that MA bid submissions, including coverage, cost-sharing, and pricing, be in a form and manner specified by the Secretary. The statute, as specified in paragraphs (a)(1), (a)(3), and (a)(6), requires that bids include the plan type, the plan's geographic service area, projected enrollment under the plan, bid amounts for the provision of Part C benefits, bid amounts for Part D benefits (if offered by the MA plan), descriptions of beneficiary cost-sharing liability for each type of benefit, the plan's use of the beneficiary rebate (if any), and the actuarial basis for determining the bid pricing amounts. Part C benefits include basic benefits (that is, the benefits available under Original Medicare Parts A and B) and non-Medicare supplemental benefits (both mandatory and optional); supplemental benefits may include benefits not available under Original Medicare (for example, vision and dental benefits) or the reduction in cost-sharing obligations of enrollees compared to Original Medicare.

The regulation at § 422.254 addresses the content of the bid submission as well but does not specify the form or manner of the submission. We developed standardized templates for MAOs to populate and upload to our Health Plan Management System (HPMS) as the bid submission described in the statute and regulation. These standardized MA bid submission templates collect the information required under § 422.254, and organize the information as follows:

- Plan Benefit Package (PBP) information (describing the Part C benefits and cost-sharing for each MA plan);
- Service Area information (identifying geographic areas where an MA plan is to be offered by the MAO);
- Plan Crosswalk information (identifying plan consolidations, terminations, and/or service area changes from one year to the next); and
- The MA bid pricing data for each PBP (that is, each MA plan). MA bid pricing data is uploaded to HPMS in a template referred to as the MA Bid Pricing Tool (MA BPT).

Currently, we publicly release information on the Plan Benefit Package, service area, and plan crosswalks each year. These data sets can be found on our Web site at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/index.html,* under the subpages Benefits-Data, MA-Contract-Service-Area-by-State-County, and Plan-Crosswalks, respectively.

In this rule, we propose to release MA bid pricing data, as defined at proposed § 422.272, which would be implemented as a release of data housed in the MA BPT for each MA plan subject to specified exclusions from release (noted in this section of the proposed rule). The MA BPT is a standardized Excel workbook with multiple worksheets and special functions built-in (for example, validation features). There are also separate BPTs used to price two types of MA plans: Medicare Medical Savings Account plans (the MSA BPT); and End-Stage Renal Disease-only special needs plans (the ESRD–SNP BPT). The MSA BPT was first released for calendar year (CY) 2009 bidding, and the ESRD–SNP BPT was first released for CY 2014 bidding. We maintain and update these three MA BPT formats under OMB #0938–0944, and release annual versions every April.

The MA BPT templates can be found on our Web site at *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Bid-Forms-Instructions.html,* accompanied by instructions on how to populate the tool and a data dictionary for all data elements. Information pertaining to the MSA BPT and the ESRD–SNP BPT can be found in the Appendices within the general MA BPT instructions, which can be found on the Bid-Forms Web site.

Below we describe the general categories of MA bid pricing data contained in the MA BPT templates, indicating the associated BPT worksheet. Worksheets 1 through 6 of the MA BPT template collect information for the development and identification of the revenue requirements for basic benefits and mandatory supplemental benefits. Optional supplemental benefits, which enrollees may opt to purchase separately, are addressed in a separate worksheet. The BPT as a whole collects the information described in § 422.254(b), (c) and (d) for coordinated care and private fee-for-service plans and in § 422.254(b) and (e) for MA–MSA plans. The regulation describes the required bid elements in general terms, which we implemented and operationalized at a detailed level in the BPT.

a. MA Base Period Experience and Projection Assumptions (MA BPT Worksheet 1)

MAOs must report base period experience data, which is defined as claims incurred in the calendar year 2 years prior to the contract year for which the bid is being submitted, for basic benefits and mandatory supplemental benefits. For example, for CY 2017 bids (which must be submitted June 6, 2016), the base period data is for CY 2015. For the historical period, MAOs report the plan's actual allowed per member per month (PMPM) cost, unit cost and utilization by service type (for example, inpatient, outpatient, etc.); cost sharing and net costs are also reported. MAOs must also report actual enrollment and revenue, as well as expenses for claims, administration, and gain/loss margin, for this base period. Finally, MAOs must report the assumptions they use to project (that is, trend) the base period claims experience to the contract year for which they are bidding.

b. MA Projected Allowed Costs (MA BPT Worksheet 2)

MAOs provide the projected allowed PMPM costs, unit costs, and utilization by service type for the contract year, using the claims experience and projection assumptions described previously; such information demonstrates the actuarial bases of the bid. Allowed costs are "gross" costs, that is, before the application of any beneficiary cost sharing. Total projected allowed costs are reported separately for dual eligible beneficiaries without full Medicare cost-sharing liability versus other beneficiaries. MAOs may also enter manual rates and the credibility assumptions used to blend together manual rates with projected experience.

c. MA Projected Cost Sharing (MA BPT Worksheet 3)

MAOs present the effective value of a plan's level of cost-sharing by service type, which must include both in-network and out-of-network cost sharing (copays and coinsurance) and other amounts such as plan deductibles and the plan's out-of-pocket maximum cost-sharing amount.

d. MA Projected Revenue Requirement (MA BPT Worksheet 4)

MAOs then combine their allowed cost data and cost sharing information (described in sections III.E.2.b. and c. of this proposed rule) to calculate the plan's projected revenue requirement, which consists of benefit costs (direct medical costs) net of cost-sharing, non-benefit expenses (administrative costs), and gain/loss margin. The plan's projected revenue requirement is allocated to the following: Medicare-covered A/B services, prescription drug coverage (if the plan is an MA–PD plan), and non-Medicare covered services (mandatory supplemental benefits under the plan).[7] MAOs report the revenue requirement separately for dual eligible beneficiaries without full Medicare cost-sharing liability versus other enrolled beneficiaries. They also report administrative expenses by category (for example, direct versus indirect administration) and information related to the plan's gain/loss (profit) margin.

MAOs have the option of reporting enrollment, revenue and expense information related to their plan enrollees with End Stage Renal Disease (ESRD) on worksheet 4; these costs are otherwise excluded from bid development. (We have the authority to determine whether and when it is appropriate to apply the bidding methodology to ESRD MA enrollees, as set forth at § 422.254(a)(2).) MAOs also have the option of reporting information related to Medicaid revenue and expenses for dual eligible beneficiaries.

The plan's expected risk profile (average risk score) is reflected in the projected revenue requirements (costs) for both A/B and supplemental bid amounts. That is, the projected costs will reflect the expected risk profile of that plan's population because the utilization projections built into the costs projected in the bid reflect the underlying risk and need for services of the expected enrollees for that plan. When these projected costs are divided by the plan's projected risk score for a projected enrollment, the costs become "standardized." Standardized costs have a risk score equal to one, which means that they reflect the risk profile of the average Medicare beneficiary.

e. MA BPT Benchmark (Worksheet 5)

The MA BPT illustrates development of the plan-specific A/B benchmark, based on the service area of the plan and the county rates (or MA regional rates) applicable to the plan; the benchmark is identified and calculated using information provided by the plan and county rate information announced by CMS. See § 422.254 and § 422.258. The service-area level benchmark represents the upper limit that the federal government will pay PMPM for coverage of A/B benefits in the defined service area, given the plan's quality rating, prior to risk adjusting payments. The service-area level benchmark for (non-regional) plans that cover multiple counties is a weighted average of the projected plan enrollment and the applicable county ratebook amounts.

For benchmark development, the MAO reports the following: Projected enrollment in member months per county; projected average risk score for the projected enrollment in each county in the plan's service area; and a plan-level factor for the proportion of beneficiaries with Medicare as Secondary Payer. Plan-level projected member months and risk scores are reported separately for dual eligible beneficiaries without full Medicare cost-sharing liability versus other beneficiaries.

The MA BPT is programmed to compare the A/B bid amount from the MAO to the benchmark to determine whether the plan has a beneficiary rebate (defined at § 422.266) and must submit information required by § 422.254(d). If the plan A/B bid amount is lower than the plan benchmark, a percentage of the difference determines the beneficiary rebate amount (where the percentage is based on the plan's quality rating). If the bid is greater than benchmark, the plan must charge a member premium for coverage of A/B benefits.

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[7] We are not proposing to release any Part D bid pricing data as part of this proposed rule. Therefore, for any MA–PD bid, the Part D information underlying the pricing of Part D benefits would be redacted from any data release under this rule. However, the amount of beneficiary rebate applied to buy-down the Part D premiums if any, is included at § 422.264(b)(2) as a use of Part C dollars, so will be included in the MA bid pricing data release. See section III.E.3.a.1.

f. MA Bid Summary (MA BPT Worksheet 6)

The MA BPT presents a summary of key figures developed in the tool, including the bid, benchmark, projected risk score, and rebate amount, to support the final step of bid pricing—development of the beneficiary premium (if any) for the plan. To determine the premium, MAOs indicate how the rebate amount will be allocated. Under § 422.266(b), the rebate must be allocated to some combination of MA mandatory supplemental benefits (defined at § 422.2), which can include buy down of original Medicare A/B cost-sharing and offering additional benefits not covered by original Medicare; and buy down of the Part D basic premium, the Part D supplemental premium, and/or the Part B premium.

g. Optional Supplemental Benefits (MA BPT Worksheet 7)

MAOs may offer optional supplemental benefits, which plan enrollees may opt to purchase for a separate, additional premium. MAOs present the actuarial pricing elements for any optional supplemental benefit packages to be offered during the contract year, up to a maximum of 5 packages. Not all MA plans offer optional supplemental benefits. MAOs report projected member months, allowed costs PMPM, cost sharing, administrative costs and gain/loss margin for each optional supplemental benefit package. MAOs also report base period experience for optional supplemental benefits, including revenue, enrollment, claim expenses, administrative expenses, and gain/loss margin. The information is reported separately as enrollees must make a separate election to purchase these benefits, and for coordinated care plans and private fee-for-service plans they cannot be funded by beneficiary rebates.

h. MSA BPT and ESRD–SNP BPT

Regarding the MSA BPT and ESRD–SNP BPT, the same general requirements apply: Submission of base period experience data; projected allowed costs by service type; projected enrollee cost-sharing payments; projected revenue requirements (medical, administrative, and margin); and development of the plan benchmark against which the bid is compared. Unique to the MSA BPT is development of the beneficiary deposit amount for the high-deductible plan. Unique to the ESRD–SNP BPT are service categories such as dialysis and nephrologist.

i. Additional Documentation

In addition to the categories of data noted in this section of the proposed rule, MAOs must also submit supporting documentation to substantiate the actuarial basis of pricing and an actuarial certification of the bid for their MA BPTs, MSA BPTs, and ESRD–SNP BPTs, as required at §§ 422.254(b)(5) and 422.256(c)(5).

3. Proposed Regulatory Changes for Release of MA Bid Pricing Data

We are proposing to amend our MA regulations to provide for the release of certain MA bid pricing data. We propose to release to the public each year, after the first Monday in October, MA bid pricing data that we accepted or approved for a contract year at least 5 years prior to the upcoming calendar year, subject to specific exclusions described in proposed § 422.272(c). We believe this disclosure is consistent with Presidential directives to make information available to the public, and with our goals of allowing public evaluation of the MA program, encouraging research into better ways to provide health care, and reporting to the public regarding federal expenditures and other statistics involving this program. For example, MA bid pricing data (which contains actual and projected cost figures) could be used to understand patterns of health care utilization such as how projected and actual costs may differ across geographic areas and different beneficiary populations, which could inform future bidding and payment policies. Further, releasing pricing data, particularly in conjunction with information already released under § 422.504(n), will provide insight into the use of public funds for the MA program, providing appropriate transparency about the administration of the program.

We propose to codify the requirements for release of MA bid pricing data for MA plan bids accepted or approved by us by adding a new § 422.272 to subpart F of part 422. First, we discuss the definition of MA bid pricing data, then our proposal to release MA bid pricing data for MA plan bids accepted or approved by us, and the types of information we propose be excluded from these data releases. Next, we discuss the specific proposal for the timing of the public data release. Finally, we solicit public comment on approaches to releasing more recent MA bid pricing data. We also solicit comment on our goals and purposes stated above for the release of MA bid pricing data.

(a) Terminology

At § 422.272(a), we propose a definition of MA bid pricing data to mean the information that MAOs must submit for the annual bid submission for each MA plan, in a form and manner specified by us. Specifically, we propose that MA bid pricing data includes the information described at § 422.254(a)(1) and the information required for MSA plans at § 422.254(e). We use § 422.254(a)(1) in our proposed definition because it provides an overview of the submission requirements in our MA bidding regulations. Specifically, § 422.254(a)(1) references § 422.254(b), (c), and (d), which address, respectively, general bid requirements, information required for coordinated care plans and private fee-for-service plans, and information on beneficiary rebates. At § 422.272(a)(2), we propose to include in the definition the information required for bids for MSA plans, set forth at § 422.254(e), which includes the amount of plan deductible for the high-deductible plan.

By proposing to define MA bid pricing data at § 422.272(a) using cross-references to existing regulation at § 422.254(a)(1) and (e), we are proposing in operational terms that the term encompass all plan-specific data fields in the MA BPT, the MSA BPT, and the ESRD–SNP BPT, that is, the figures that MAOs input and those that are calculated within the BPT. The BPTs also include data that are not plan-specific, which consist of look-up tables built-in to facilitate calculations. We do not propose to include these look-up tables as part of the proposed definition of MA bid pricing data, as they are not submitted by the MAO. These look-up tables are hidden Excel worksheets (which can be "unhidden" within Excel), and are currently available to the public in the BPT templates on the CMS Web site at *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Bid-Forms-Instructions.html.* Selected data from the look-up tables are reflected in each MA plan's BPT. For example, there is a look-up table in the BPTs with the county rates for the contract year and when the MAO enters a state-county code, the BPT extracts the appropriate rate amount for the county from the look-up table and populates the appropriate data field.

Our proposed definition of MA bid pricing data references elements required at § 422.254(b) and includes information described in section III.E.2. (MA Bid Pricing Data) of this proposed rule: The estimated revenue required by an MA plan for providing original

Medicare benefits and mandatory supplemental health care benefits, if any (composed of direct medical costs by service type, administrative costs and return on investment); and the plan pricing of enrollee cost-sharing for original Medicare benefits and mandatory supplemental benefits. In addition, the definition references the MA bid pricing data elements required at § 422.254(c), which include more detail about the Medicare-covered and supplemental bid amounts such as the actuarial bases for the bid amounts, projected enrollment, and data specific to regional MA plans.

Finally, we propose to define MA bid pricing data to include elements required at § 422.254(d), thus incorporating a reference to the forms of beneficiary rebate at § 422.266(b). That is, for plans that bid below the benchmark for their service areas, the term would include the beneficiary rebate amounts that are allocated in the BPTs to the uses allowed in law: Reduction of cost-sharing below original Medicare levels, offering additional benefits not covered by original Medicare, and reduction of the Part D basic premium, the Part D supplemental premium, and/or the Part B premium. Unlike the underlying components of the Part D pricing (that is, pricing information related to the Part D benefit analogous to the information included in the MA BPT), we consider beneficiary rebate amounts that are applied to reduce the Part D basic and supplemental premiums to be Part C amounts that are part of the MA bid pricing submission, not the Part D bid pricing submission.

(b) Release of Accepted or Approved MA Bid Pricing Data With a 5 Year Lag

In § 422.272(b), we propose to authorize the public release of MA bid pricing data for the MA plan bids that were accepted or approved by us for a contract year under § 422.256. We propose that the annual release will contain MA bid pricing data from the final list of MA plan bids accepted or approved by us for a contract year that is at least 5 years prior to the upcoming calendar year.

We use the phrase "accepted or approved" in the proposed regulation text because both terms are used in existing regulation when referring to MA bids. We consider these words to mean the same thing in the context of MA bid pricing submissions, and we use both words in proposed § 422.272(b) to mirror existing regulation. For example, existing § 422.256(b) states that CMS can only accept bids that meet the standards in that paragraph. However, § 422.256(b)(4)(i) and (ii) use the phrase "CMS approves a bid. . . ." The phrases "decline to accept" and "decline to approve" are used at § 422.254(a)(5) and § 422.256(a), respectively. In the remainder of this preamble, we will use the term "accepted" to represent the phrase "accepted or approved."

During our annual bid review process, we determine which MAOs must submit one or more updated versions of the initial MA BPT for one or more of their MA plans, in response to questions from our bid reviewers. In addition, as part of the bid pricing submission process, an MAO may have to adjust its allocation of beneficiary rebate dollars for some or all of its MA plans that offer Part D and for their regional PPOs, after we publicly release the Part D national average bid amount and the final MA regional plan benchmarks. Any reallocation of rebate dollars results in a revised MA bid, which must be submitted to us as an updated version of the original submission. Finally, on occasion an MAO will withdraw an MA plan after we have accepted the plan bid. For these reasons, we propose that the MA bid pricing data to be released will only be the data found in the final list of accepted bids; for operational purposes, this means the final accepted MA BPTs, MSA BPTs, and ESRD–SNP BPTs, subject to exclusions noted in proposed paragraph (c).

Finally, in § 422.272(b), we propose to authorize the annual release of MA bid pricing data for a contract year that is at least 5 years prior to the upcoming calendar year. We believe that 5 years is an appropriate length of time for the MA bid pricing data to no longer be competitively sensitive. (The base period data on actual expenses in the MA BPT, MSA BPT, and ESRD–SNP BPT is 2 years older than the data for the bidding year—see the description of the MA BPT category MA Base Period Experience and Projection Assumptions in section III.E.2. of this proposed rule.) Since this will be an annual release, over time the public would have the ability to trend bid cost projections across years, to compare actual costs from the MA BPT with projections from prior years, and to observe bidding patterns over ever-longer periods of time.

We are seeking to balance the protection of commercially sensitive information with our goals to effectively administer federal health care programs, increase data transparency regarding federal expenditures, and encourage research into better ways to provide health care. We propose that a 5-year delay renders multi-year comparisons of pricing trends less relevant to the current year of MA plan pricing. The time lag represents a buffer between the development and implementation of pricing strategies that can be distilled from data multiple years for and the observed relationship and trend from one year to the next, thus mitigating possible competitive disadvantage from the proposed data disclosure. For example, an MAO looking to enter a new MA market is significantly less likely to gain an unfair commercial advantage from being able to examine and trend 5-year-old bid pricing data than if the MAO were able to examine and trend more recent bid pricing data.

We solicit comment on the proposed 5 year delay for reducing competitive disadvantages to MAOs. We solicit comments explaining whether a shorter period would suffice to protect MAOs from competitive harm associated from the disclosure of confidential commercial information or if a longer period is necessary to adequately protect the information and assure the continued submission of accurate data.

(c) Exclusions From Release

In § 422.272(c), we propose that several types of MA bid pricing information be excluded from the data releases under paragraph (b). First, we note that we are not proposing to release Part D bid pricing data in this rule. For this reason, the exclusion from release at proposed § 422.272(c)(1) is information pertaining to the Part D prescription drug bid amount for an MA plan offering Part D benefits, specifically the information required for Part D bid submission at § 422.254(b)(1)(ii), (c)(3)(ii), and (c)(7). We consider this exclusion at proposed § 422.272(c)(1) to include the following amounts in the MA BPT that pertain to the Part D premiums: The Part D basic premium before and after application of beneficiary rebate amounts; the Part D supplemental premium before and after application of beneficiary rebate amounts; the combined MA plus Part D total plan premium; and the target Part D basic premium.

Regarding Part D bid pricing data, section 1860D–15(f) of the Act contains protections for data submitted by Part D Sponsors in accordance with section 1860D–15; these protections would generally prohibit public release of such data. We propose that the Part D bid pricing elements listed in this section of the proposed rule, which appear in the MA bid pricing tools, would be excluded from release. However, we note that the Part C statute does not establish similar protections for MA bid pricing data, and we believe that MA bid pricing data is not subject to the protections imposed by section 1860D–15 of the Act.

Second, at § 422.272(c)(2), we propose to exclude from release two categories of additional information that we require to verify the actuarial bases of the MA plan bids. At paragraph (c)(2)(i), we propose to exclude from release any narrative information in the MA BPT, MSA BPT, and ESRD SNP BPT regarding base period factors, manual rates, cost-sharing methodology, optional supplemental benefits, or other topics for which narratives are required by us under § 422.254. These narrative fields provide additional information to allow us to verify the actuarial bases of the bid, as described at § 422.256(c)(5). For the base period narratives, MAOs are asked to describe the source of the base period experience data, and any other utilization adjustment factors, unit cost adjustment factors, and additive adjustment factors that the MAO applied. For projected allowed costs, the narrative field captures descriptions of manual rates including trending assumptions in the manual rates. For projected cost sharing, the narrative fields contains a description of the methodology for reflecting the impact of maximum cost-sharing. Finally, for optional supplemental benefits, there is a general comments field. The proposed regulation text would also exclude from release any other narrative fields in the BPT that we may require as the bid submission process changes over time. We propose to exclude these text fields in the BPTs. MAOs may populate them with information pertinent to more than the individual MA plan bid in which the narrative is included, such as regional or national-level information on an MAO's approach to cost-sharing methodology or projection factors. For example, MAOs may provide information on provider contracting, such as the fee schedules. Further, these explanations and additional information provide insight into the exercise of actuarial judgment in developing the bids. We believe that it is reasonable to treat such summary statements of MAO methodology or strategy as information proprietary to the MAO that should remain protected from public disclosure. The release of such information (for example, fee schedules or national pricing strategy) may provide an unfair commercial advantage to certain entities, such as new market entrants, and likely would impair the government's ability to obtain such information in the future, since MAOs have greater discretion in deciding what written information to share with us and would likely attempt to avoid sharing fee schedule and pricing strategy information.

Another category of information that we propose to exclude from release, at § 422.272(c)(2)(ii), is the supporting documentation that MAOs submit to us to support the actuarial bases of each MA plan bid; these materials are collected outside of the BPT templates so this proposed exclusion would be operationalized by withholding from release any materials submitted as part of an MA bid that were not part of the BPT worksheet submission. Supporting documentation for each MA plan bid can consist of multiple text, spreadsheet, and email files. MAOs submit the first round of supporting documentation with the initial bid submission. Subsequently, during the bid review process, our reviewers may communicate requests for additional supporting documentation, and in response, MAOs may submit multiple updated versions of an MA plan's BPT and additional supporting documentation. There are no standard formats for supporting documentation. A range of files (Word, Adobe, Excel, and email formats) may be uploaded for each of the MA plan bids, and there is no way to identify clearly which data elements in any of the supporting documentation for an MA plan bid applies to the final accepted version of the bid. Supporting documentation often links a particular plan bid to an MAO's broader pricing approaches, such as financial arrangements with providers, and we believe that such analytical information at a regional or national level could be commercially sensitive information in a way that the cost and enrollment estimates in the BPT are not, since such strategic pricing and contracting information could provide an unfair commercial advantage to certain entities, such as new market entrants, who would not need to release such strategic information. We also are concerned whether release of supporting documentation could have a chilling effect on the scope of information provided by MAOs for future bidding and our ability to accurately evaluate bids. We rely on MAOs to provide detailed explanations of the bids in order for CMS to fully understand the judgment calls underlying the assumptions reflected in the bids. If MAOs believe that the explanations and additional information are not protected from disclosure, they may provide less information and less explanation. In order to preserve the access we have, we are proposing to protect this information.

Third, at § 422.272(c)(3), we propose to exclude from release any information identifying Medicare beneficiaries and other individuals. We believe that this identifying information should be excluded from a public data release to protect the privacy of individuals, including but not limited to protecting the confidentiality of information about Medicare beneficiaries. Regarding Medicare beneficiaries, we propose to exclude from release any MA bid pricing data element that is based on fewer than 11 Medicare beneficiaries as we believe that this threshold establishes the point at which individual-level data can be discerned. Following our longstanding data release policy for protecting individually identifiable information, in the event that data fields in an MA BPT, MSA BPT, or ESRD SNP BPT are populated with fewer than 11 MA plan members (or 132 member months, assuming each individual is counted for 12 months), we would suppress all of those data fields in the public release file for that MA plan bid under our proposed rule. We are not proposing to build this threshold into the regulation text, however, as we believe that technology and the ability to reverse-engineer data to identify beneficiaries may change over time. We may revisit this threshold as we administer the data releases proposed here (and in other Medicare contexts) and will make adjustments as necessary to ensure that we do not disclose data that could be used to identify beneficiaries. For example, data fields with member months, utilizers, and utilization per 1,000 could be populated based on fewer than 11 MA plan members and would be suppressed from the release under this proposed rule. Protection of information that could identify Medicare beneficiaries, particularly in the context of their receipt of health care services, is a long-standing principle of ours in the context of the Medicare program. Incorporating this principle and the necessary protection of this data into this proposal to disclose information is appropriate.

Regarding other individuals, we require the names and contact information of certifying actuaries and MA plan contacts in the MA bid submission, that is, in certain fields in the MA BPT, MSA BPT, and ESRD–SNP BPT, and we also require the names and contact information in the actuarial certifications submitted by actuaries who prepared the bids. We propose to exclude this information from the release that we propose to implement. The actuarial certification consists of standardized language that we developed for the purpose of bidding; for example, the language notes that the actuary is a member of the American Academy of Actuaries, federal law and CMS guidance regarding MA bids were followed, the data and assumptions used in the development of the bid are reasonable, and Actuarial Standards of Practice were applied. (Certifying actuaries may choose whether to append additional language.) We do not believe that these bid certification paragraphs represent information that serves the goals for this proposed release of MA bid pricing data (for example, to inform research and public evaluation of the MA program and to be transparent about spending). In addition, identifying specific individuals who have worked on a bid for an MAO appears an unnecessary intrusion into the personal privacy of these individuals. In sum, we propose to not release any information identifying individual actuaries or their associated certification paragraphs, to protect individual names and to not expend resources separating names from each of the hundreds of identical or similar paragraphs of attestation language.

Finally, at § 422.272(c)(4), we propose to exclude from release bid review correspondence between us (including our contractors) and the MAO, and internal bid review reports (for example, bid desk review documentation housed in the HPMS Bid Desk Review module, which supports the automated aspects of bid review). First, bid review correspondence (emails) often involves follow-up questions requesting clarification of supporting documentation, so our concerns described above regarding the release of supporting documentation apply to bid review correspondence. Second, it would not be operationally feasible to determine which set of bid review emails between our reviewers and MAOs and which internal bid review reports pertain to the final accepted/approved bid for an MA plan, which is the data we propose to release.

(d) Timing of MA Bid Pricing Data Release

At § 422.272(d), we propose the timing of the release of MA bid pricing data as provided in paragraph (b) and limited by the exclusions in paragraph (c). We propose that the annual release would occur after the first Monday in October. We selected the first Monday in October as the date after which the release could occur each year because the annual bidding cycle has come to a close at this point and we have completed the approval of MA plan bids for the upcoming contract year (calendar year). For example, after the first Monday in October 2016, the bids for contract year 2017 have been accepted; thus, a public release in December 2016 or January 2017 would be a release of the final accepted MA bid pricing data for a contract year not more recent than 2012.

Under this example, our December 2016 release of MA bid pricing data under this proposed rule may include the following: (1) The accepted MA BPT worksheets for 2012 in their entirety, subject to the exceptions § 422.272(c); (2) the accepted MSA BPT worksheets for 2012 in their entirety, subject to the same exceptions; (3) accepted MA BPTs for 2006 through 2011, subject to the same exceptions; and (4) MSA BPTs for 2009 through 2011 (as 2009 was the first year this BPT was used), subject to the same exceptions, because these years are more than 5 years prior to 2017. However, under the example of a December 2016 release, we would not release any Part C pricing data for ESRD–SNPs because the ESRD–SNP BPT was used for the first time for contract year 2014; the first time that data from accepted ESRD–SNP BPTs could be released under this proposal is after the first Monday in October 2018.

While we propose to authorize release of this data after the first Monday in October each year, we are not committing to a specific date for each annual release. We will provide details on each year's release schedule through sub-regulatory communications. We anticipate that as the release process becomes more standardized over the years, we will be able to release these files closer to the proposed regulatory timeline. In addition, we intend that the first time we implement a public release MA bid submission data, we may release data for multiple contract years that meet the criterion of at least 5 years prior to the upcoming calendar year.

As mentioned in the Background (section III.E.1), in crafting this proposal to release MA bid pricing data, we are seeking to balance proprietary interests with our mission to effectively administer federal health care programs and increase data transparency. We are soliciting comments on the approach we are proposing for the public release of MA bid pricing data based on a 5-year lag in the data, and whether that is the appropriate timeframe to apply to this data release. We also seek comment on the scope of the proposed release of BPT worksheets and data elements. We are particularly interested in whether of the MA bid pricing data we are proposing to release contains proprietary information, and if so, are requesting detailed explanations of good cause for its redaction from public availability and suggestions for what safeguards might be implemented to appropriately protect those portions of the data. Detailed explanations should contain specific examples which show how this information disclosure could cause substantial competitive harm to MAOs. Specific examples should (1) cite the particular information proposed to be released and explain how that information differs from publicly available data; (2) point to the particular entity or entity type that could gain an unfair competitive advantage from the information release; and (3) fully explain the mechanism by which the release of that particular information would create an unfair competitive advantage for that particular entity. Similarly, we are interested in comments that our proposed scope for release is too narrow and unnecessarily protects data that is not confidential and should not be protected. We are soliciting comments and explanations that show how the data is not confidential, could not be used to create unfair competitive disadvantage, and that its release would not have a chilling effect on the nature and scope of the data that we currently receive from MAOs in the bid submissions. As noted above, we view this rulemaking as the opportunity to solicit wide ranging comments on this issue in order to chart the wisest course for release of pricing data in support of our goals.

4. Proposed Technical Change

We propose to amend § 422.250 on the basis and scope of the MA program to add a reference to section 1106 of the Act. As discussed in the Background (section E.1.), section 1106(a) of the Act (42 U.S.C. 1306(a)) provides us the authority to enact regulations that would enable the agency to release information filed with this agency.

5. Other Approaches To Release of MA Bid Pricing Data

We are also considering whether to release MA bid pricing data for years more recent than the 5-year data lag proposal. In 2011, an academic researcher submitted a request to CMS for certain data elements regarding the 2009 MA Base Period Experience in the 2011 MA bid pricing submissions. We rejected the request under Exemption 4 to the FOIA, 5 U.S.C. 552(b)(4), which exempts from disclosure trade secrets and confidential or privileged commercial or financial information that is obtained from a person. In a 2013 opinion, *Biles* v. *Dep't of Health and Human Services,* 931 F. Supp. 2d 211 (D.D.C. 2013), the U.S. District Court for the District of Columbia ordered the release of the requested bid information, rejecting HHS's argument that release would cause substantial competitive harm to the private companies that submit bid data to CMS. The court remarked that the HHS statements about substantial competitive harm were conclusory. As a result of this ruling, we released the requested data to the academic researcher (and the public) at *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/DataRequests.html*. In light of this litigation, as well as anticipated additional requests for more recent MA bid pricing data, we are soliciting public comments on a range of approaches we could implement to release data more recent than the proposal we are currently setting forth for consideration.

For example, we are considering whether to release MA bid pricing data on a shorter timeframe than the proposed 5-year lagged timeframe, which could be as recent as MA bid pricing data from the previously-concluded MA contract year. We are also seeking comment as to whether the relationship between the passage of time and commercial sensitivity of the bid data changes more rapidly for some MA bid pricing data elements than others. If commenters believe this to be the case, we are seeking the submission of detailed analysis that sets forth which data elements meet this standard and why.

If unfair competitive harm is included as a rationale for us to consider in withholding some or all elements of more recent MA bid pricing data from release, either to external researchers subject to some limitations in redisclosure of the data or the public at large, we seek evidence of this competitive harm linked to particular bid data elements, and a fulsome discussion as to how each of the elements identified could be used by a competitor to directly harm a competing MAO. See section III.E.3.d above for detail on what a fulsome discussion would include, in our explanation of "specific examples." If there are commercially sensitive data elements in the MA bids, we also seek comment as to whether there are safeguards that might be appropriately implemented to protect those identified data elements, while still allowing releases of more recent data.

Finally, we are seeking comment regarding to whom we should release more recent MA bid pricing data. Specifically, should such a release be made fully available to the public at large, or only to researchers who have studies approved through an application process and who are subject to our long-standing data sharing procedures. If we were to release MA bid pricing data for years more recent than the 5 year lagged data we propose here, we also seek comment on whether to use the existing policies for the release of Part D prescription drug event (PDE) data at § 423.505(m) and Part C encounter data at § 422.310(f)(2). We also seek comment on whether research results from the analysis of MA bid pricing data should be subject to additional restrictions, such as a prohibition of publication of MA bid pricing data at the plan level or prohibitions on the identification of the applicable MAO that submitted the data. We seek comment on whether external researchers should be able to use MA bid pricing data for commercial purposes rather than to produce research that could be useful to us in our administration of the Medicare program generally. We are considering limiting conditions of this type as means to release as much data while protecting what should be protected.

As discussed in section III.E.3.d above, we are seeking comment on our proposal that 5 years is an appropriate length of time for the MA bid pricing data we are proposing to release to no longer be competitively sensitive. In addition, in setting forth this section III.E.5 discussion, we are also soliciting comments on how we can best serve the needs of the public through the sharing of MA bid pricing data that is less than 5 years old while at the same time addressing the concerns of MAOs that we appropriately guard against the potential misuse of data in ways that would undermine protections put in place to ensure nondisclosure of proprietary data. The purpose of this solicitation is to both inform our decision-making process about the 5-year threshold proposed above, as well as to inform future policy development.

6. Background on Part C and Part D Medical Loss Ratio Data

Section 1103 of Title I, Subpart B of the Health Care and Education Reconciliation Act (Pub. L. 111–152) amends section 1857(e) of the Act to add medical loss ratio (MLR) requirements to Medicare Part C. An MLR is expressed as a percentage, generally representing the percentage of revenue used for patient care rather than for such other items as administrative expenses or profit. Because section 1860D–12(b)(3)(D) of the Act incorporates by reference the requirements of section 1857(e) of the Act, these MLR requirements also apply to the Part D program. In the May 23, 2013 final rule (78 FR 31284), we codified the MLR requirements for MAOs and Part D sponsors in the regulations at part 422, subpart X, and part 423, subpart X.

For contracts beginning in 2014 or later, MAOs, cost plans, and Part D sponsors are required to report their MLRs and are subject to financial and other penalties for a failure to meet the statutory requirement that they have an MLR of at least 85 percent (see § 422.2410 and § 423.2410). The statute imposes several levels of sanctions for failure to meet the 85 percent minimum MLR requirement, including remittance of funds to CMS, a prohibition on enrolling new members, and ultimately contract termination. The minimum MLR requirement in section 1857(e)(4) of the Act creates incentives for MAOs and Part D sponsors to reduce administrative costs, such as marketing costs, profits, and other uses of the funds earned by plan sponsors, and helps to ensure that taxpayers and enrolled beneficiaries receive value from Medicare health plans.

Under the regulations at § 422.2410 and § 422.2460, with respect to MAOs, and § 423.2410 and § 423.2460, with respect to Part D sponsors, for each contract year, each MAO and Part D sponsor is required to submit a report to us, in a timeframe and manner that we specify, which includes the data needed to calculate and verify the MLR and remittance amount, if any, for each contract. The information that MAOs and Part D sponsors report to us includes incurred claims for medical services and prescription drug costs, expenditures on activities that improve health care quality, taxes, licensing and regulatory fees, non-claims costs, and revenue.

We have developed a standardized MLR Report template, called the MLR Report, for MAOs and Part D sponsors to populate with the data used to calculate the MLR and remittance amount owed to us under § 422.2410 and § 423.2410, if any. The MLR Report is a standardized Excel workbook with three worksheets and special functions built in (for example, validation features). We maintain and update the MLR Report data collection format under OMB #0938–1232.

For each contract year beginning in 2014 or later, MAOs and Part D sponsors are required to enter their MLR data and upload their MLR Reports to our Health Plan Management System (HPMS). Based on the data entered by the MAO or Part D sponsor, the Report calculates the MLR for the contract. An MA or Part D contract's MLR is increased by a credibility factor if the contract's experience for the contract year is partially credible in actuarial terms, as provided at § 422.2440 and § 423.2440. Finally, we also require MAOs and Part D sponsors to include in their MLR Reports a detailed description of the methods used to allocate expenses, including how each specific expense meets the criteria for the expense category to which it was assigned. The MLR Report is on our Web site at *https://www.cms.gov/Medicare/Medicare-Advantage/Plan-Payment/medicallossratio.html,* accompanied by instructions on how to populate the Report.

Below we describe the categories of Part C and Part D MLR data submitted in the MLR Reports:

- *Revenue.* MAOs and Part D sponsors must report revenue received under the contract. The MLR Report includes separate lines for MAOs and Part D sponsors to report the amounts of revenue received, such as beneficiary premiums; MA plan payments (based on A/B bids); MA rebates; Part D direct subsidies; federal reinsurance subsidies; Low Income Premium Subsidy Amounts; risk corridor payments; and MSA enrollee deposits (see § 422.2420(c)(1) and § 423.2420(c)(1)).
- *Claims.* MAOs and Part D sponsors must report incurred claims for clinical services and prescription drug costs, including categories such as the following: Direct claims paid to providers (including under capitation contracts with physicians) for covered services; for an MA contract that includes MA–PD plans, or a Part D contract, the MLR Report must include drug costs provided to all enrollees under the contract; liability and reserves for claims incurred during the contract year; paid and accrued medical incentive pools and bonuses; reserves for contingent benefits and the medical or Part D claim portion of lawsuits; MA rebate amounts that are used to reduce enrollees' Part B premiums; total fraud reduction expenses and total claim payment recoveries as a result of fraud reduction efforts; MSA enrollee deposits; and direct and indirect remuneration (see § 422.2420(b) and § 423.2420(b)).
- *Federal and State Taxes and Licensing or Regulatory Fees.* The MLR Report includes MAOs and Part D sponsors' outlays for taxes and fees, such as federal income taxes and other federal taxes; state income, excise, business, and other taxes; state premium taxes; allowable community benefit expenditures; and licensing and regulatory fees (see § 422.2420(c)(2) and § 423.2420(c)(2)).
- *Health Care Quality Improvement Expenses Incurred.* MAOs and Part D sponsors must enter their expenditures for health care quality improvement. Expenditures are categorized separately depending on the primary purpose of the activity. Quality improvement expenses are reported in categories such as: (1) Expenses for improving health outcomes through the implementation of activities such as quality reporting, effective case management, care coordination, chronic disease management, and medication and care compliance initiatives; (2) expenses for implementing activities to prevent hospital readmissions; (3) expenses for activities primarily designed to improve patient safety, reduce medical errors, and lower infection and mortality rates; (4) expenses for activities primarily designed to implement, promote, and increase wellness and health activities; (5) expenditures to enhance the use of health care data to improve quality, transparency, and outcomes and support meaningful use of health information technology; or (6) allowable ICD–10 implementation costs (see § 422.2430(a)(1) and § 423.2430(a)(1)).
- *Non-Claims Costs.* MAOs and Part D sponsors must report expenditures for non-claims costs, such as administrative fees, direct sales salaries and benefits, brokerage fees and commissions, regulatory fines and penalties, cost containment expenses not included as quality improvement expenses, all other claims adjustment expenses, non-allowable community benefit expenditures, and non-allowable ICD–10 implementation costs (see § 422.2430(b) and § 423.2430(b)).
- *Employer Group Waiver Plan (EGWP) Reporting Methodology.* We only apply the MLR requirement to the Medicare-funded portion of EGWPs. MLR Reports submitted for MA or Part D contracts that include EGWPs must specify the percentage of the contract's total revenue that was funded by Medicare. The MLR Report must also identify the methodology that the MAO or Part D sponsor used to determine the Medicare-funded portion of the EGWP (see § 422.2420 and § 423.2420).
- *Total Member Months.* MAOs and Part D sponsors must report all member months across all plans under the contract (see § 422.2440 and § 423.2440).
- *Plan-Specific Data.* MAOs and Part D sponsors enter a list of all of the plans offered under the contract, and the member months associated with each plan entered. They must provide additional details about each plan that is listed, including whether the plan is a Special Needs Plan for beneficiaries who are dually eligible for both Medicare and Medicaid (D–SNP); whether the plan's defined service area includes counties in one of the territories; and plan-level cost and revenue information for D–SNPs in territories (see § 422.2420(a) and § 423.2420(a)).
- *Medical Loss Ratio Numerator.* This is a calculated field that is the sum of all amounts reported as claims or as health care quality improvement expenses in the MLR Report (see § 422.2420(b) and § 423.2420(b)).
- *Medical Loss Ratio Denominator.* This field is calculated by taking the contract's total revenue and deducting the sum of the reported licensing or regulatory fees, federal and state taxes, and allowable community benefit expenditures (see § 422.2420(c) and § 423.2420(c)).
- *Credibility Adjustment.* An MAO or Part D sponsor may add a credibility adjustment to a contract's MLR if the contract's experience is partially credible, as determined by us (see § 422.2440(d) and § 423.2440(d)). If a contract receives a credibility adjustment (determined by the number of total member months under the contract), this field is populated by a percentage that represents the credibility adjustment factor (see § 422.2440(a) and § 423.2440(a)).
- *Unadjusted MLR.* This is a calculated field that reflects the MLR for an MA or Part D contract before application of the credibility adjustment (see § 422.2440 and § 423.2440).
- *Adjusted MLR.* This is a calculated field that represents the MLR after the application of the credibility adjustment factor (see § 422.2440(a) and § 423.2440(a)).
- *Remittance Amount Due to CMS for the Contract Year.* The MLR Report includes any amounts that the MAO or Part D sponsor must remit to us. The MLR Report identifies the amount of the remittance that is allocated to Parts A and B, and the amount allocated to Part D (see § 422.2410(c) and § 423.2410(c)).

7. Proposed Regulatory Changes for Release of MLR Data

a. Proposed Addition of § 422.2490 and § 423.2490 Authorizing Release of Part C and Part D Medical Loss Ratio Data

We are proposing to add new contract requirements, codified in new regulations at §§ 422.504 and 422.2490 of part 422, with respect to Part C MLR data, and §§ 423.505 and 423.2490 of part 423, with respect to Part D MLR data, to authorize release to the public by CMS of certain MLR data submitted by MAOs and Part D sponsors. We propose to define Part C MLR data at § 422.2490(a), and Part D MLR data at

§ 423.2490(a), as the data the MAOs and Part D sponsors submit to us in their annual MLR Reports, as required under existing § 422.2460 and § 423.2460. At § 422.2490(b) and § 423.2490(b), we propose certain exclusions to the definitions of Part C MLR data and Part D MLR data, respectively. Finally, we propose at § 422.2490(c) and § 423.2490(c) to release the Part C MLR data and Part D MLR data, respectively, for each contract for each contract year, no earlier than 18 months after the end of the applicable contract year.

Generally, the MLR for each MA and Part D contract reflects the ratio of costs (numerator) to revenues (denominator) for all enrollees under the contract. For an MA contract, the MLR reflects the percentage of revenue received under the contract spent on incurred claims for all enrollees, prescription drug costs for those enrollees in MA plans under the contract offering the Part D benefit, quality initiatives that meet the requirements at § 422.2430, and amounts spent to reduce Part B premiums. The MLR for a Part D contract reflects the percentage of revenue received under the contract spent on incurred claims for all enrollees for Part D prescription drugs, and on quality initiatives that meet the requirements at § 423.2430. The percentage of revenue that is used for other items such as administration, marketing, and profit is excluded from the numerator of the MLR (see § 422.2401 and § 423.2401; § 422.2420(b)(4) and § 423.2420(b)(4); § 422.2430(b) and § 423.2430(b)).

As discussed in section III.F.1. of this proposed rule, our proposed release of Part C and Part D MLR data is in keeping with Presidential initiatives to improve federal management of information resources by increasing data transparency and access to federal datasets. In proposing this release, we are also seeking to align with current disclosures of MLR data that issuers of commercial health plans submit each year as required by section 2718 of the Public Health Service Act. We have published similar commercial MLR data on our Web site at *https://www.cms.gov/CCIIO/Resources/Data-Resources/mlr.html*.

The MLR data that we propose to release will enable enrollees, consumers, regulators, and others to see how much of plan sponsors' revenue is used to pay for services, quality improving activities, and Part B premium rebates versus how much is used to pay for "non-claims," or administrative expenses, incurred by the plan sponsor. We believe that the release of this data will facilitate public evaluation of the MA and Part D programs by providing insight into the efficiency of health insurers' operations. In addition, we believe that our proposed policy for the release of certain MLR data will provide beneficiaries with information that can be used to assess the relative value of Medicare health and drug plans.

b. Exclusions From the Release of Part C and Part D MLR Data

For the purpose of this data release under proposed § 422.2490 and § 423.2490, we would exclude four categories of information from the release of Part C and Part D MLR data, as described at proposed § 422.2490(b) and § 423.2490(b), respectively. First, at § 422.2490(b)(1) and § 423.2490(b)(1), we propose to exclude from release any narrative information that MAOs and Part D sponsors submit to support the amounts that they include in their MLR Reports, such as descriptions of the methods used to allocate expenses. MAOs and Part D sponsors are required to describe the methods they used to allocate expenses, including incurred claims, quality improvement expenses, federal and state taxes and licensing or regulatory fees, and other non-claims costs. A detailed description of each expense element should be provided, including how each specific expense meets the criteria for the type of expense in which it is categorized. We believe that descriptions of expense allocation methods should be excluded because MAOs and Part D sponsors may be required to provide information that is pertinent to more than the individual MA or Part D contract for which the MLR Report is being submitted (see, for example, § 422.2420(d)(1)(ii) and § 423.2420(d)(1)(ii), which requires that expenditures that benefit multiple contracts, or contracts other than those being reported, be reported on a pro rata share), such as an MAO's or Part D sponsor's proprietary approach to setting payment rates in contracts with providers, or its strategies for investing in activities that improve health quality. We are concerned that MAOs and Part D sponsors would be reluctant to submit narrative descriptions that include information that they regard as proprietary if they know that it will be disclosed to the public, which could impair our ability to assess the accuracy of their allocation methods.

Second, at § 422.2490(b)(2) and § 423.2490(b)(2), we propose to exclude from release any plan-level information that MAOs and Part D sponsors submit in their MLR Reports. Some of the plan-level data in MAO's and Part D sponsors' MLR Reports is also included in their plan bids as base period experience data, such as plan IDs, plan member months, and Medicaid per member per month gain/loss. As discussed in our proposal to release certain MA bid pricing data, we believe bid data would no longer be competitively sensitive after 5 years; however, we do not believe that bid data becomes no longer competitively sensitive within the 18-month timeframe for our proposed release of MLR data. Therefore, we will exclude from our proposed release plan-level data that is included as base period experience data in plan bids. We also propose to exclude the plan-level information submitted in MLR Reports because we do not regard it as relevant to the purposes of our proposed release of Part C and Part D MLR data, which include giving the public access to data that can be used to evaluate the efficiency of MAOs and Part D sponsors and providing enrollees with information that can be used to compare the relative value of health plans. For example, our proposed release would exclude MAOs' and Part D sponsors' responses to questions in the MLR Report that ask whether each plan under a contract is a Special Needs Plan for beneficiaries who are dually eligible for both Medicare and Medicaid (D–SNP), or whether the plan's defined service area includes counties in one of the territories.

Third, at § 422.2490(b)(3) and § 423.2490(b)(3), we propose to exclude from release any information identifying Medicare beneficiaries or other individuals. This exclusion is proposed for the same reason we propose to exclude similar information from MA bid submission data that will be released; we believe that it is important to protect the privacy of individuals identified in these submissions, particularly Medicare beneficiaries. Protection of information that could identify Medicare beneficiaries, particularly in the context of their receipt of health care services, is a long-standing principle of ours in the context of the Medicare program. Incorporating this principle and the necessary protection of this data into this proposal to disclose information is appropriate. With respect to Medicare beneficiaries, we propose to exclude from release any information (that is, data elements) in an MLR Report for a contract if the total number of beneficiaries under the contract is fewer than 11, as we believe that this threshold establishes the point at which individual-level data can be discerned. Following our longstanding data release policy for protecting individually identifiable information, if a data field in the MLR Report for an MA or Part D contract is calculated based on figures associated with fewer than 11 enrollees (or 132 member months, assuming each individual is counted for 12 months), we would suppress all the data from such fields in the public release file for that contract. We are not proposing to build this threshold into the regulation text, however, as we believe that as technology changes and the ability to reverse-engineer data to identify beneficiaries may change over time. We may revisit this threshold as we administer the data releases proposed here (and in other Medicare contexts) and will make adjustments as necessary to ensure that we do not disclose data that could be used to identify beneficiaries.

Regarding other individuals, we require that MAOs and Part D sponsors provide in their MLR Reports the names and contact information of individuals who can answer questions about the data submitted in an MLR Report. We propose to exclude this information from release. We do not believe that the release of this information serves the purposes of our proposed release of certain MLR data, which are to provide the public with data that can be used to evaluate MA and Part D contracts' efficiency, and to provide beneficiaries with information that can be used to compare the relative value of Medicare plans. Further, release of this identifying and contact information appears to be an unnecessary intrusion into information about private individuals.

Fourth, at § 422.2490(b)(4) and § 423.2490(b)(4), we propose to exclude from release any MLR review correspondence. In the course of the MLR review process, our reviewers may engage in correspondence with MAOs and Part D sponsors in order to validate amounts included in their MLR Reports. Such correspondence may include requests for evidence of amounts reported to us. Responses to these requests could include competitively-sensitive information, such as MAOs' and Part D sponsors' negotiated rates of reimbursement. Release of this correspondence could cause MAOs to be less forthcoming in the information provided to CMS, which would impede the ability of the agency to verify the information submitted by MAOs and Part D sponsors.

c. Timing of Release of Part C and Part D MLR Data

We are proposing to release the MLR data specified in this rule for each MA and Part D contract on an annual basis no earlier than 18 months after the end of the contract year to which the MLR data applies. We are proposing to follow the commercial MLR approach in making the data we receive in MLR Reports available to the public. For Part C and Part D MLR reporting, the data is due about 12 months after the end of the contract year. After we receive MAOs' and Part D sponsors' MLR Reports, we anticipate that it will take up to six months for us to review and finalize the data submitted by MAOs and Part D sponsors.

We believe that our proposed release of contract-level MLR data strikes the appropriate balance between safeguarding information that could be commercially sensitive or proprietary and providing enrollees of health plans, consumers, regulators, and others with a measure that can be used to evaluate health insurers' efficiency. The Part C MLR data and Part D MLR data that we propose to release is aggregated at the contract level. Costs in the MLR numerator are aggregated across providers, beneficiaries, and sites of service. Costs and revenues are further aggregated across all plans under the contract. We do not believe that there is a realistic possibility that the MLR data that we propose to release could be disaggregated or reverse engineered to reveal commercially sensitive or proprietary information. We seek comment on this point and on our analysis of the commercial sensitivity of this information.

We believe the availability of the Part C MLR data and Part D MLR data we are proposing to release will provide beneficiaries a measure by which they can compare the relative value of Medicare products. Our proposed release of MLR data will permit enrollees of health plans, consumers, regulators, and others to take into consideration MLRs when evaluating health insurers' efficiency.

We also believe the availability of MLR data will enhance the competitive nature of the MA and Part D programs. The proposed access to data will support potential plan sponsors in evaluating their participation in the Part C and D programs and will facilitate the entry into new markets of existing plan sponsors. In knowing historical MLR data, new business partners might emerge, and better business decisions might be made by existing partners. As a result, we believe that releasing Part C and Part D MLR data as proposed is both necessary and appropriate for the effective operation of these programs.

We seek comment on the release of Part C MLR data and Part D MLR data as outlined above. We solicit comment on whether the Part C MLR data and Part D MLR data we propose to release contain proprietary information, and if so, what safeguards might be appropriate to protect those data, such as recommended fields to be redacted, the minimum length of time that such data remains commercially sensitive, and any suggestions for publishing aggregations of Part C MLR data and Part D MLR data in lieu of publishing the MLR data as submitted by MAOs and Part D sponsors. We invite commenters to provide analysis and explanations to support comments that information should be protected for a longer—or shorter—period of time so that we may properly evaluate our proposal in adopting a final rule. Analysis and explanations should (1) cite the particular information proposed to be released and explain how that information differs from publicly available data; (2) point to the particular entity or entity type that could gain an unfair competitive advantage from the information release; and (3) fully explain the mechanism by which the release of that particular information would create an unfair competitive advantage for that particular entity.

We also solicit comment on whether MLR data that is associated single-plan contracts is more commercially sensitive than MLR data that is associated with contracts that include multiple plans, and if so, whether we should take any protective measures when releasing the MLR data for single-plan contracts, such as redacting data fields that could be used to identify the contract, withholding the MLR data for all single-plan contracts and instead publishing a data set consisting of figures that have been averaged across all single-plan contracts, or by releasing a more limited data set for single-plan contracts.

8. Proposed Technical Changes

We are proposing to amend § 422.2400, which identifies the basis and scope of the MLR regulations for MAOs, and § 423.2400, which identifies the basis and scope of the MLR regulations for Part D sponsors, to add a reference to section 1106 of the Act, which governs the release of information gathered in the course of administering our programs under the Act.

F. Prohibition on Billing Qualified Medicare Beneficiary Individuals for Medicare Cost-Sharing

We remind all Medicare providers (including providers of services defined in section 1861 of the Act and physicians) that federal law prohibits them from collecting Medicare Part A and Medicare Part B deductibles, coinsurance, or copayments, from beneficiaries enrolled in the Qualified Medicare Beneficiaries (QMB) program (a Medicaid program which helps certain low-income individuals with Medicare cost-sharing liability). In July 2015, we released a study finding that confusion and inappropriate balance billing persist notwithstanding laws prohibiting Medicare cost-sharing charges for QMB individuals, Access to Care Issues Among Qualified Medicare Beneficiaries (QMB) ("Access to Care") *https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/Downloads/Access_to_Care_Issues_Among_Qualified_Medicare_Beneficiaries.pdf.*

These findings underscore the need to re-educate providers about proper billing practices for QMB enrollees.

In 2013, approximately 7 million Medicare beneficiaries were enrolled in the QMB program. State Medicaid programs are liable to pay Medicare providers who serve QMB individuals for the Medicare cost-sharing. However, as permitted by federal law, states can limit provider payment for Medicare cost-sharing to the lesser of the Medicare cost-sharing amount, or the difference between the Medicare payment and the Medicaid rate for the service. Regardless, Medicare providers must accept the Medicare payment and Medicaid payment (if any, and including any permissible Medicaid cost sharing from the beneficiary) as payment in full for services rendered to a QMB individual. Medicare providers who violate these billing prohibitions are violating their Medicare Provider Agreement and may be subject to sanctions. (See sections 1902(n)(3); 1905(p); 1866(a)(1)(A); 1848(g)(3) of the Act.)

Providers should take steps to educate themselves and their staff about QMB billing prohibitions and to exempt QMB individuals from impermissible Medicare cost-sharing billing and related collection efforts. For more information about these requirements, steps to identify QMB patients and ways to promote compliance, see *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/se1128.pdf.*

Given that original Medicare providers may also serve Medicare Advantage enrollees, we note that the CY 2017 Medicare Advantage Call Letter reiterates the billing prohibitions applicable to dual eligible beneficiaries (including QMBs) enrolled in Medicare Advantage plans and the responsibility of plans to adopt certain measures to protect dual eligible beneficiaries from unauthorized charges under § 422.504(g). (See pages 181–183 at *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2017.pdf*).

G. Recoupment or Offset of Payments to Providers Sharing the Same Taxpayer Identification Number

1. Overview and Background

Medicare payments to providers and suppliers may be offset or recouped, in whole or in part, by a Medicare contractor if the Medicare contractor or CMS has determined that a provider or supplier has been overpaid. Historically, we have used the Medicare provider billing number or National Provider Identifier (NPI) to recoup overpayments from Medicare providers and suppliers until these debts were paid in full or eligible for referral to the Department of Treasury (Treasury) for further collection action under the Debt Collection Improvement Act of 1996 and the Digital Accountability and Transparency Act of 2014. Once an overpayment is referred to Treasury, the Treasury's Debt Management Services uses various tools to collect the debt, including offset of federal payments against entities that share the same provider Taxpayer Identification Number (TIN). Hence, Treasury has the ability to collect our overpayments using the provider TIN and we pay a fee for every collection made.

On March 23, 2010, the Affordable Care Act (ACA) was enacted. Section 6401(a)(6) of the Affordable Care Act established a new section 1866(j)(6) of the Act. Section 1866j(6) of the Act allows the Secretary to make any necessary adjustments to the payments to an applicable provider of services or supplier to satisfy any amount due from an obligated provider of services or supplier. The statute defines an applicable provider of services or supplier (applicable provider) as a provider of services or supplier that has the same taxpayer identification number as the one assigned to the obligated provider of services or supplier. The statute defines the obligated provider of services or supplier (obligated provider) as a provider of services or supplier that owes a past-due overpayment to the Medicare program. For purposes of this provision, the applicable and obligated providers must share a TIN, but may possess a different billing number or National Provider Identifier (NPI) number than one another.

For example, a health care system may own a number of hospital providers and these providers may share the same TIN while having different NPI or Medicare billing numbers. If one of the hospitals in this system receives a demand letter for a Medicare overpayment, then that hospital (Hospital A) will be considered the obligated provider while its sister hospitals (Hospitals B and C) will be considered the applicable providers. This authority allows us to recoup the overpayment of the obligated provider, Hospital A, against any or all of the applicable providers, Hospitals B and C, with which it, Hospital A, shares a TIN.

2. Provisions of the Proposed Regulations

If CMS or a Medicare contractor has decided to put into effect an offset or recoupment, then § 405.373(a) requires the Medicare contractor to notify the provider or supplier in writing of its intention to fully or partially offset or recoup payment and the reasons for the offset or recoupment. Currently, the written demand letter sent by the Medicare contractor to a provider or supplier serves as notification of the overpayment and intention to recoup or offset if the obligated provider, Hospital A, fails to repay the overpayment in a timely manner.

With the passage of section 1866(j)(6) of the Act, the requirements in § 405.373(a) could be interpreted to require the Medicare contractor to provide notification to both the obligated provider, Hospital A, and the applicable provider, Hospital B, of its intention to recoup or offset payment. Because we don't think it is necessary to provide separate notice to both the obligated provider and the applicable provider, we propose to amend the notice requirement in § 405.373. Specifically, we propose to create a new paragraph (f) in § 405.373 to state that § 405.373(a) does not apply in instances where the Medicare Administrative Contractor intends to offset or recoup payments to the applicable provider of services or supplier to satisfy an amount due from an obligated provider of services or supplier when the applicable and obligated provider of services or supplier share the same Taxpayer Identification Number.

Before the effective date of this rule, we intend to notify all potentially affected Medicare providers of the implementation of section 1866j(6) of the Act through Medicare Learning Network (MLN) or MLN Connects Provider eNews article(s), an update to the current Internet Only Manual instructions including, the Medicare Financial Management Manual, and the addition of clarifying language in the demand letters issued to obligated providers. We believe these actions would provide adequate notice to providers and suppliers sharing a TIN, if they choose, provide the opportunity to implement a tracking system of Medicare overpayments on the corporate level for the affected providers. We also believe these actions are sufficient because of Treasury's analogous practice of offsetting using a TIN without furnishing notice to all potentially affected providers and suppliers. It has been a long standing practice for Treasury to offset federal payments using the TIN and Treasury currently does not issue a notice of intent to recoup or offset to applicable providers and suppliers when Treasury recoups CMS overpayments.

Additionally, in our review of § 405.373(a) and (b), we propose to replace the terms intermediary and carrier with the term Medicare Administrative Contractor as intermediaries and carriers no longer exist.

H. Accountable Care Organization (ACO) Participants Who Report Physician Quality Reporting System (PQRS) Quality Measures Separately

The Affordable Care Act gives the Secretary authority to incorporate reporting requirements and incentive payments from certain Medicare programs into the Shared Savings Program, and to use alternative criteria to determine if payments are warranted. Specifically, section 1899(b)(3)(D) of the Act affords the Secretary discretion to incorporate reporting requirements and incentive payments related to the physician quality reporting initiative (PQRI), under section 1848 of the Act, including such requirements and such payments related to electronic prescribing, electronic health records, and other similar initiatives under section 1848, and permits the Secretary to use alternative criteria than would otherwise apply (under section 1848 of the Act) for determining whether to make such payments.

Current Shared Savings Program regulations at § 425.504(c) do not allow eligible professionals (EPs) billing through the Taxpayer Identification Number (TIN) of an Accountable Care Organization (ACO) participant to participate in PQRS outside of the Shared Savings Program, and these EPs and the ACO participants through which they bill may not independently report for purposes of the PQRS apart from the ACO. This policy was designed to ease reporting burden for individual EPs and group practices and promote integration of providers and suppliers within the ACO in order to help achieve the Shared Savings Program goals of improving quality and coordination of care. While over 98 percent of ACOs satisfactorily report their quality data annually, if an ACO fails to satisfy the PQRS reporting requirements, the individual EPs and group practices participating in that ACO will receive the PQRS payment adjustment along with the automatic VM downward payment adjustment.

We are proposing to amend the regulation at § 425.504 to permit EPs that bill under the TIN of an ACO participant to report separately for purposes of the 2018 PQRS payment adjustment when the ACO fails to report on behalf of the EPs who bill under the TIN of an ACO participant. Specifically, we are proposing to remove the requirement at § 425.504(c)(2) so that, for purposes of the reporting period for the 2018 PQRS payment adjustment (that is, January 1, 2016, through December 31, 2016), EPs who bill under the TIN of an ACO participant have the option of reporting separately as individual EPs or group practices. If the ACO fails to satisfactorily report on behalf of such EPs or group practices, we are proposing to consider this separately reported data for purposes of determining whether the EPs or group practices are subject to the 2018 PQRS payment adjustment. We are also proposing to amend § 425.504(c)(2) to apply only for purposes of the 2016 payment adjustment. We propose at § 425.504(d) the revised requirements for the 2017 and 2018 PQRS payment adjustment under the Shared Savings Program. We discuss the proposed changes for the 2017 PQRS payment adjustment under the Shared Savings Program in more detail later in this section.

We note that the registration deadline for participating in the PQRS Group Practice Reporting Option (GPRO) is June 30 of the applicable reporting period. Since affected EPs are not able to register for the PQRS GPRO by the applicable deadline for the 2018 PQRS payment adjustment, we propose that such EPs would not need to register for the PQRS GPRO for the 2018 PQRS payment adjustment, but rather mark the data as group data in their submission. Thus, we are proposing to eliminate a registration process for groups submitting data using third party entities. When groups submit data utilizing third party entities, such as a qualified registry, QCDR, direct EHR product, or EHR data submission vendor, we are able to obtain group information from the third party entity and discern whether the data submitted represents group submission or individual submission once the data is submitted. In addition, we propose that an affected EP may utilize the secondary reporting period either as an individual EP using one of the registry, qualified clinical data registry (QCDR), direct Electronic Health Record (EHR) product, or EHR data submission vendor reporting options or as a group practice using one of the registry, QCDR, direct EHR product, or EHR data submission vendor reporting options. We note that this would exclude, for individual EPs, the claims reporting option and, for group practices, the Web Interface and certified survey vendor reporting options.

Furthermore, we recognize that certain EPs are similarly situated with regard to the 2017 PQRS payment adjustment, which will be applied beginning on January 1, 2017. We believe it is appropriate and consistent with our stated policy goals to afford these EPs the benefit of this proposed policy change. Accordingly, as noted above,we are proposing to permit EPs that bill through the TIN of an ACO participant to report separately for purposes of the 2017 PQRS payment adjustment if the ACO failed to report on behalf of the EPs who bill under the TIN of an ACO participant. Specifically, we are proposing to remove the requirements at § 425.504(c)(2) so that, for purposes of the reporting period for the 2017 PQRS payment adjustment, EPs who bill under the TIN of an ACO participant have the option of reporting separately as individual EPs or group practices. As noted above, we are proposing to amend § 425.504(c)(2) to apply only for purposes of the 2016 payment adjustment. We propose at § 425.504(d) the revised requirements for the 2017 and 2018 PQRS payment adjustment under the Shared Savings Program.

The previously established reporting period for the 2017 PQRS payment adjustment is January 1, 2015, through December 31, 2015. To allow affected EPs that participate in an ACO to report separately for purposes of the 2017 PQRS payment adjustment, we are proposing at § 414.90(j)(1)(ii) to establish a secondary PQRS reporting period for the 2017 PQRS payment adjustment for individual EPs or group practices who bill under the TIN of an ACO participant if the ACO failed to report on behalf of such individual EPs or group practices during the previously established reporting period for the

2017 PQRS payment adjustment. This option is limited to EPs that bill through the TIN of an ACO participant in an ACO that failed to satisfactorily report on behalf of its EPs and would not be available to EPs that failed to report for purposes of PQRS outside the Shared Savings Program.

In addition, we propose that these affected EPs may utilize the secondary reporting period either as an individual EP using the registry, QCDR, direct EHR product, or EHR data submission vendor reporting options or as a group practice using one of the registry, QCDR, direct EHR product, or EHR data submission vendor reporting options. We note that this would exclude, for individual EPs, the claims reporting option and, for group practices, the Web Interface and certified survey vendor reporting options.

We note that the registration deadline for the participating in the PQRS GPRO is June 30 of the applicable reporting period. Since the applicable deadline for the 2017 PQRS payment adjustment has passed, we propose that such EPs would not need to register for the PQRS GPRO for the 2017 PQRS payment adjustment, but rather would be able to report as a group practice via the registry, QCDR, direct EHR product, or EHR data submission vendor reporting options. Therefore, we propose at § 414.90(j)(4)(v) that sections § 414.90(j)(8)(ii), (iii), and (iv) would apply to affected EPs reporting as individuals using this secondary reporting period for the 2017 PQRS payment adjustment. In addition, we propose at § 414.90(j)(7)(viii) that sections § 414.90(j)(9)(ii), (iii), and (iv) would apply to affected EPs reporting as group practices using this secondary reporting period for the 2017 PQRS payment adjustment. Further, we propose at § 414.90(k)(4)(ii) that § 414.90(k)(5) would apply to affected EPs reporting as individuals or group practices using this secondary reporting period for the 2017 PQRS payment adjustment.

We are also proposing that the secondary reporting period for the 2017 PQRS payment adjustment would coincide with the reporting period for the 2018 PQRS payment adjustment (that is, January 1, 2016 through December 31, 2016). In addition, for operational reasons and to minimize any additional burden on affected EPs (who are already required to report for CY 2016 for purposes of the 2018 PQRS payment adjustment), we propose to assess the individual EP or group practice's 2016 data using the applicable satisfactory reporting requirements for the 2018 PQRS payment adjustment (including, but not limited to, the applicable PQRS measure set). We invite comment on any 2018 requirements that may need to be modified when applied for purposes of the 2017 PQRS payment adjustment,

As a result, individual EP or group practice 2016 data could be used with respect to the secondary reporting period for the 2017 payment adjustment or for the 2018 payment adjustment or for both payment adjustments if the ACO in which the affected EPs participate failed to report for purposes of the applicable payment adjustment. We believe this change to our program rules is necessary for affected individual EPs and group practices to be able to take advantage of the additional flexibility proposed at section III.K.1.e. for the Shared Savings Program. If an affected individual EP or group practice decides to use the secondary reporting period for the 2017 payment adjustment, it is important to note that this EP or group practice should expect to receive a PQRS payment adjustment for services furnished in 2017 until CMS is able to determine that the EP or group practice satisfactorily reported for purposes of the 2017 PQRS payment adjustment. First, we would need to process the data submitted for 2016. Second, we would need to determine whether or not the individual EP or group practice met the applicable satisfactory reporting requirements for the 2018 PQRS payment adjustment. Third, we would need to update the individual EP or group practice's status so that the EP or group practice stops receiving a negative payment adjustment on claims for services furnished in 2017 and reprocess all claims that were previously paid. In addition, as discussed further in section III.L. of this proposed rule, the EP or group practice would also avoid the automatic downward VM adjustment, but would not qualify for an upward adjustment since the ACO failed to report.

Since EPs and group practices taking advantage of this secondary reporting period for the 2017 PQRS payment adjustment will have missed the deadline for submitting an informal review request for the 2017 PQRS payment adjustment, we propose the informal review submission periods for these EPs or group practices would occur during the 60 days following the release of the PQRS feedback reports for the 2018 PQRS payment adjustment.

We request comments on these proposals.

I. Medicare Advantage Provider Enrollment

1. Background

a. General Overview

The Medicare program is the primary payer of health care for approximately 54 million beneficiaries and enrollees. Section 1802(a) of the Act permits beneficiaries to obtain health services from any individual or organization qualified to participate in the Medicare program. Providers and suppliers furnishing items or services must comply with all applicable Medicare requirements stipulated in the Act and codified in the regulations. These requirements are meant to promote quality care while protecting the integrity of the program. As a major component of our fraud prevention activities, we have increased our efforts to prevent unqualified individuals or organizations from enrolling in Medicare.

The term "provider of services" is defined in section 1861 of the Act as a hospital, a critical access hospital (CAH), a skilled nursing facility (SNF), a comprehensive outpatient rehabilitation facility (CORF), a home health agency (HHA), or a hospice. The term "supplier" is defined in section 1861(d) of the Act as, unless context otherwise requires, a physician or other practitioner, facility or other entity (other than a provider of services) that furnishes items or services under title XVIII of the Act. Other supplier categories may include, for example, physicians, nurse practitioners, and physical therapists.

Providers and suppliers that fit into these statutorily defined categories may enroll in Medicare if they meet the proper screening and enrollment requirements. This proposed rule would require MA organization providers and suppliers to be enrolled in Medicare in an approved status. We generally refer to an "approved status" as a status whereby a provider or supplier is enrolled in, and is not revoked from, the Medicare program. For example, a provider or supplier that has submitted an application, but has not completed the enrollment process with their respective Medicare Administrative Contractor (MAC), is not enrolled in an approved status. The submission of an enrollment application does not deem a provider or supplier enrolled in an approved status. A provider or supplier that is currently revoked from Medicare is not in an approved status. Out-of network or non-contract providers and suppliers are not required to enroll in

Medicare to meet the requirements of this proposed rule.

b. Background

To receive payment for a furnished Medicare Part A or Part B service or item, or to order, certify, or prescribe certain Medicare services, items, and drugs, a provider or supplier must enroll in Medicare. The enrollment process requires the provider or supplier to complete, sign, and submit to its assigned Medicare contractor the appropriate Form CMS–855 enrollment application. The CMS–855 application form captures information about the provider or supplier that is needed for CMS or its contractors to screen the provider or supplier and determine whether the provider or supplier meets all Medicare requirements. This screening prior to enrollment helps to ensure that unqualified individuals and entities do not bill Medicare and that the Medicare Trust Funds are accordingly protected. Data collected and verified during the enrollment process generally includes, but is not limited to: (1) Basic identifying information (for example, legal business name, tax identification number); (2) state licensure information; (3) practice locations; and (4) information regarding ownership and management control.

We strive to further strengthen its provider and supplier enrollment process to prevent and deter problematic providers and suppliers from entering the Medicare program. This includes, but is not limited to, enhancing its program integrity monitoring systems and revising its provider and supplier enrollment regulations in 42 CFR 424, subpart P, and elsewhere as needed. With authority granted by the Act, including provisions in the Affordable Care Act and Medicare Access and CHIP Reauthorization Act, we have revised our provider and supplier enrollment regulations by issuing the following:

- In the February 2, 2011 **Federal Register** (76 FR 5861), we published a final rule with comment period titled, "Medicare, Medicaid, and Children's Health Insurance Programs; Additional Screening Requirements, Application Fees, Temporary Enrollment Moratoria, Payment Suspensions and Compliance Plans for Providers and Suppliers." This final rule with comment period implemented major Affordable Care Act provisions, including the following:

++ A requirement that institutional providers and suppliers must submit application fees as part of the Medicare, Medicaid, and CHIP provider and supplier enrollment processes.

++ Establishment of Medicare, Medicaid, and CHIP provider and supplier risk-based enrollment screening categories and corresponding screening requirements.

++ Authority that enabled imposition of temporary moratoria on the enrollment of new Medicare, Medicaid, and CHIP providers and suppliers of a particular type (or the establishment of new practice locations of a particular type) in a geographic area.

- In the April 27, 2012 **Federal Register** (77 FR 25284), we published a final rule titled, "Medicare and Medicaid Programs; Changes in Provider and Supplier Enrollment, Ordering and Referring, and Documentation Requirements and Changes in Provider Agreements." The rule implemented another major Affordable Care Act provision and required, among other things, that providers and suppliers that order or certify certain items or services be enrolled in or validly opted-out of the Medicare program.

++ This requirement was expanded to include prescribers of Medicare Part D drugs in the final rule published in the May 23, 2014 **Federal Register** (79 FR 29844) titled, "Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs."

Through improved processes and systems, since March 2011 we have:

- Saved over $927 million by revoking Medicare Part A and B providers and suppliers that did not comply with Medicare requirements;
- Avoided over $2.4 billion in costs by preventing further billing from revoked and deactivated Medicare Part A and B providers and suppliers;
- Deactivated more than 543,163 Medicare Part A and B providers and suppliers that did not meet Medicare enrollment standards;
- Revoked enrollment and billing privileges under § 424.535 for more than 34,888 Medicare Parts A and B providers and suppliers that did not meet Medicare enrollment standards, and
- Denied 4,949 applications for providers and suppliers in Medicare Parts A and B that did not meet Medicare enrollment standards within a recent 12-month period.[8]

The public may review CMS' Reports to Congress each year for more information on program integrity efforts, including how we calculate savings to the Medicare and Medicaid programs. The Department of Health and Human Services Office of Inspector General (OIG), Government Accountability Office (GAO), and other federal agencies routinely review Medicare's provider and supplier enrollment processes and systems, including a recent study stating that "as part of an overall effort to enhance program integrity and reduce fraud risk, effective enrollment-screening procedures are essential to ensure that ineligible or potentially fraudulent providers or suppliers do not enroll in the Medicare program." (GAO–15–448) The enrollment screening authorities granted in the Affordable Care Act and used to prevent and detect ineligible or potentially fraudulent providers and suppliers from enrolling in the Medicare program are working to protect beneficiaries and the Medicare Trust Funds.

Under applicable provisions of the Tax Equity and Fiscal Responsibility Act (TEFRA) of 1982, Medicare began to pay health plans on a prospective risk basis for the first time. The Balanced Budget Act of 1997 (BBA) modified these provisions and established a new Part C of the Medicare program, known as Medicare+Choice (M+C), effective January 1999. As part of the M+C program, the BBA authorized us to contract with public or private organizations to offer a variety of health plan options for enrollees, including both traditional managed care plans (such as those offered by HMOs, as defined in section 1876 of the Act) and new options not previously authorized.

The M+C program was renamed the Medicare Advantage (MA) program under Title II of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173), which was enacted on December 8, 2003. The MMA updated and improved the choice of plans for enrollees under MA and changed how benefits are established and payments are made. Under the MMA, enrollees may choose from additional plan options. In addition, Title I of the MMA established the Medicare prescription drug benefit (Part D) program and amended the MA program to allow most MA plans to offer prescription drug coverage.

All Medicare health plans, with the exception of PACE organizations, operating in geographic areas that we determine to have enough qualified providers and suppliers with which to contract in order for enrollees to have access to all Medicare Part A and Part B services, must develop a network of qualified providers and suppliers that meet our network adequacy standards. As a condition of contracting with us, the health plans' contracted network of providers and suppliers must be approved by us as part of application approval (§ 417.406). PACE organizations must furnish comprehensive medical, health, and social services that integrate acute and long-term care in at least the PACE center, the participant's home, or inpatient facilities, and must ensure accessible and adequate services to meet the needs of its participants. Under current guidance, Medicare health plans may include in their networks providers and suppliers that are not enrolled in Medicare.

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[8] Taken from Shantanu Agrawal, M.D. testimony to Congress on July 22, 2015 *http://www.aging.senate.gov/imo/media/doc/CMS%20_Agrawal_7_22_15.pdf.*

2. Provisions of the Proposed Regulation

a. Need for Regulatory Action

This proposed rule would require providers or suppliers that furnish health care items or services to a Medicare enrollee who receives his or her Medicare benefit through an MA organization to be enrolled in Medicare and be in an approved status. The term "MA organization" refers to Medicare Advantage plans and also MA plans that provide drug coverage, otherwise known as an MA–PD plan. This proposal would create consistency with the provider and supplier enrollment requirements for all other Medicare (Part A, Part B, and Part D) programs. We believe that this proposed rule is necessary to help ensure that Medicare enrollees receive items or services from providers and suppliers that are fully compliant with the requirements for Medicare enrollment and that are in an approved enrollment status in Medicare. This proposed rule would assist our efforts to prevent fraud, waste, and abuse and to protect Medicare enrollees by carefully screening all providers and suppliers, especially those that potentially pose an elevated risk to Medicare, to ensure that they are qualified to furnish Medicare items and services. Out-of network or non-contract providers and suppliers are not required to enroll in Medicare to meet the requirements of this proposed rule.

We consider provider and supplier enrollment to be the gateway to the Medicare program and to beneficiaries. Requiring enrollment of those that wish to furnish Medicare items or services gives us improved oversight of the providers and suppliers treating beneficiaries and the Medicare Trust Funds dollars spent on their care. However, Medicare does not have direct oversight over all providers and suppliers in MA organizations. We note that § 422.204 requires MA organizations to conduct screening of their providers. We believe that we, through our enrollment processes, can further ensure that only qualified providers and suppliers treat Medicare beneficiaries by conducting rigorous screening and rescreening of providers and suppliers that include, for example, risk-based site visits and, in some cases, fingerprint-based background checks. We also has access to information not available to MA organizations, making oversight to ensure compliance with all federal and state requirements more robust. We also continually review provider and supplier enrollment information from multiple sources, such as judicial, law enforcement, state licensure, professional credentialing, and other databases. In short, we collect and carefully review and verify information prior to the provider's or supplier's enrollment and, of great importance, continue this monitoring throughout the period of enrollment. Section 422.204, on the other hand, neither requires MA organizations to, for instance, review a provider or supplier's final adverse action history (as defined in § 424.502), nor to verify a provider or supplier's practice location, ownership, or general identifying information.

We believe that MA organization enrollees should have the same protections against potentially unqualified or fraudulent providers and suppliers as those afforded to beneficiaries under the fee-for-service and Part D programs. Indeed, Medicare beneficiaries and enrollees, the Medicare Trust Funds, and the program at large, are at risk when providers and suppliers that have not been adequately screened and reviewed furnish, order, certify, or prescribe Medicare services and items and receive Medicare payments. For instance, a network provider with a history of performing medically unnecessary tests, treatments, or procedures could threaten enrollees' welfare, as could a physician who routinely overprescribes dangerous drugs. This could also result in improper Medicare payments, harming the Medicare Trust Funds and taxpayers. Requiring enrollment allows us to have proper oversight of providers and suppliers. Under the provisions of this proposed rule, if a provider or supplier fails to meet our requirements or violates federal rules and regulations, we may revoke their enrollment, thereby removing them from consideration as an MA organization provider or supplier.

Information regarding a provider or supplier's enrollment status is housed in our enrollment repository called the Provider Enrollment, Chain and Ownership System (PECOS). A link to that information is located on the CMS Web site. Initial data show a large percent of Medicare Advantage providers and suppliers are already enrolled in Medicare. We do not believe that this proposed rule would have a significant impact on MA organizations' ability to establish networks of contracted providers that meet CMS' MA network requirements. However, we are soliciting industry comment on the potential impact of this proposed rule on MA organizations ability to establish or maintain an adequate networks of providers.

We believe that preventing questionable providers or suppliers from participating in the MA program and removing existing unqualified providers and suppliers would help ensure that fewer enrollees are exposed to risks and potential harm, and that taxpayer monies are spent appropriately. Such a policy would also help comply with the GAO's recommendation that we improve its provider and supplier enrollment processes and systems to increase the protection of all beneficiaries and the Medicare Trust Funds. (GAO–15–448). The additional resources and oversight that we provide in its processes for enrolling providers and suppliers will enhance and complement the screening processes that MA organizations already are required to perform.

b. Statutory Authority

The following are the principal legal authorities for our proposed provisions:

- Section 1856(b) of the Act provides that the Secretary shall establish by regulation other standards for Medicare+Choice organizations and plans "consistent with, and to carry out, this part." In addition, § 1856(b) states that these standards supersede any state law or regulation (other than those related to licensing or plan solvency) for all MA organizations.
- Sections 1102 and 1871 of the Act, which provide general authority for the Secretary to prescribe regulations for the efficient administration of the Medicare program.
- Section 1866(j) of the Act, which provides specific authority with respect to the enrollment process for providers and suppliers in the Medicare program.

3. Major Provisions

Given the foregoing and the need to safeguard the Medicare program and its enrollees, we propose several provisions in this proposed rule.

Although existing regulations at § 422.204 address basic requirements for MA provider credentialing, we propose in § 422.204(b)(5) to require plans to verify that they are compliant with the provider and supplier enrollment requirements. We believe this addition would help facilitate MA organizations' compliance.

In §§ 422.222, 417.478, 460.68, and 460.32, we propose to add a requirement that providers and suppliers enroll in Medicare in an approved status in order to provide health care items or services to a Medicare enrollee who receives his or her Medicare benefit through an MA organization. This requirement would apply to network providers and suppliers; first-tier, downstream, and related entities (FDR); providers and suppliers participating in the Program of All-inclusive Care for the Elderly (PACE); suppliers in Cost HMOs or CMPs; providers and suppliers participating in demonstration programs; providers and suppliers in pilot programs; locum tenens suppliers; and incident-to suppliers. MA organizations that do not ensure that providers and suppliers comply with the provider and supplier enrollment requirements may be subject to sanctions and termination. Considering the serious risks to the Medicare program and enrollees from fraudulent or unqualified providers and suppliers, we believe that these are appropriate sanctions.

Current rules allow MA organizations to contract with different entities to provide services to beneficiaries. These contracted entities are referred to as first-tier, downstream, and related entities or FDRs, as defined in § 422.500.

PACE is a Medicare and Medicaid program that helps people meet their health care needs in the community instead of going to a nursing home or other care facility, wherein a team of health care professionals works with participants and their families to make sure participants get the coordinated care they need. A participant enrolled in PACE must receive Medicare and Medicaid benefits solely through the PACE organization. To ensure consistency within our programs, we believe that our proposed provider and supplier enrollment requirements should extend to this program.

Medicare Cost HMOs or CMPs are a type of Medicare health plan available in certain areas of the country. Some Cost HMOs or CMPs only provide coverage for Part B services. Cost HMOs or CMPs do not include Part D. These plans are either sponsored by employer or union group health plans or offered by companies that do not provide Part A services.

Demonstrations and pilot programs, also called research studies, are special projects that test improvements in Medicare coverage, payment, and quality of care. They usually operate only for a limited time for a specific group of people and/or are offered only in specific areas. Providers and suppliers in these programs would not be exempt from the requirements of this proposed rule.

In § 422.224, we also propose to prohibit MA organizations from paying individuals or entities that are excluded by the OIG or revoked from the Medicare program. In this proposal, there would be a first time allowance for payment; as part of this, the MA organization would be required to notify the provider or supplier and the enrollee that no future payment shall be made to, or on behalf of, the revoked or excluded provider or supplier. We believe such notification is necessary because enrollees and beneficiaries often do not know when their provider or supplier is excluded by the OIG or revoked from Medicare. We understand that MA organizations have little or no notice when enrollees seek out-of-network providers and suppliers and only obtain this information once an item or service has been provided. It is probable that some out-of-network providers or suppliers cannot meet Medicare enrollment requirements and therefore may be unable to enroll. We believe the proposals included in this proposed rule will allow for notification to be given to the enrollee and the provider or supplier that no further payments shall be made. We believe such excluded or revoked individuals and entities pose a significant risk to enrollees and should not receive federal dollars, even if payment is made through an intermediary such as an MA organization.

In § 422.501(c)(2), we propose to add to language to the MA organization application requirements requiring MA organizations to provide documentation that all applicable providers and suppliers are enrolled in Medicare in an approved status. We believe that this would assist CMS in the MA organization application process by requiring MA organizations to provide assurance that the designated providers and suppliers are properly screened and enrolled in Medicare.

In § 422.504(a)(6), we propose to add language to the conditions to which an MA organization must agree in its contract with us. MA organizations must agree to comply with all applicable provider requirements in subpart E of this part, including provider certification requirements, anti-discrimination requirements, provider participation and consultation requirements, the prohibition on interference with provider advice, limits on provider indemnification, rules governing payments to providers, and limits on physician incentive plans. In § 422.504(a)(6), we propose to extend this requirement to suppliers, not just limit it to providers. In this same section, we also propose to add a requirement at for MA organizations to comply with the provider and supplier enrollment requirements referenced in § 422.222. We believe these revisions would help facilitate the MA plan's compliance with § 422.222.

In §§ 422.504(i)(2)(v), 417.484, and 460.70, we propose to add provisions that requires MA organizations, Cost plans, and PACE organizations to require all FDRs and contracted entities to agree to comply with the provider and supplier enrollment provision.

In §§ 422.510(a)(4)(xiii) and 460.50, we propose provisions that would give us the authority to terminate a contract if an MA organization or PACE organization fails to meet provider and supplier enrollment requirements in accordance with § 422.222 and payment prohibitions in § 422.224. This section is necessary to ensure plan compliance with §§ 422.222 and 422.224 and to provide an appropriate remedy with respect to plans that fail to comply.

We also propose to add provisions to §§ 422.752(a) and 460.40 that would give us the authority to impose sanctions if an MA organization or PACE organizations fails to meet provider and supplier enrollment requirements in accordance with §§ 422.222 and 422.224. As with proposed § 422.510(a)(13), we believe this section is necessary to ensure plan compliance with §§ 422.222 and 422.224 and to furnish an appropriate remedy regarding plans that do not comply.

Finally, we propose to make these provisions effective the first day of the next plan year that begins 2 years from the date of publication of the CY 2017 PFS final rule with comment period.

We believe this would give all stakeholders sufficient time to prepare for these requirements. We are unable to impose new requirements on MA organizations mid-year and therefore must wait to make these rules effective. We seek public comment on our proposed effective date.

J. Proposed Expansion of the Diabetes Prevention Program (DPP) Model

1. Background

In January 2015, the Administration announced the vision of "Better Care, Smarter Spending, Healthier People" with emphases on improving the way providers are paid, improving and innovating in care delivery, and sharing information to support better decisions.

Diabetes is at epidemic levels in the Medicare population, affecting more than 25 percent of Americans aged 65 or older.[9] Care for Americans aged 65 and older with diabetes accounts for roughly $104 billion annually, and these costs are growing; by 2050, diabetes prevalence is projected to increase 2 to 3 fold if current trends continue.[10] Fortunately, Type 2 diabetes is typically preventable with appropriate lifestyle changes.

A diabetes prevention program is an evidence-based intervention targeted to individuals with prediabetes, meaning those who have blood sugar that is higher than normal but not yet in the diabetes range. The risk of progression to Type 2 diabetes in an individual with prediabetes is around 5–10 percent per year, or about 5–20 times higher than in individuals with normal blood glucose.[11] The National Diabetes Prevention Program (DPP) administered by the Centers for Disease Control and Prevention (CDC), is a structured health behavior change program delivered in community and health care settings by trained community health workers or health professionals. The National DPP consists of 16 intensive "core" sessions of a CDC-approved curriculum in a group-based setting that provides practical training in long-term dietary change, increased physical activity, and problem-solving strategies for overcoming challenges to sustaining weight loss and a healthy lifestyle. After the 16 core sessions, monthly maintenance sessions help to ensure that the participants maintain healthy behaviors. The primary goal of the intervention is to reduce incidence of Type 2 diabetes by achieving at least 5 percent average weight loss among participants. To learn more about the National DPP please visit *http://www.cdc.gov/diabetes/prevention/lifestyle-program/index.html.*

In 2012, the Center for Medicare & Medicaid Innovation (the Innovation Center) awarded a Health Care Innovation Award (HCIA) to The Young Men's Christian Association (YMCA) of the USA (Y–USA) to test whether DPP services could be successfully furnished by non-physician, community-based organizations to Medicare beneficiaries diagnosed with prediabetes and therefore at high risk for development of Type 2 diabetes. The HCIA model tests are being conducted under the authority of section 1115A of the Act (added by section 3021 of the Affordable Care Act) (42 U.S.C. 1315a). The statute authorizes the Innovation Center to test innovative health care payment and service delivery models that have the potential to reduce Medicare, Medicaid, and Children's Health Insurance Program (CHIP) expenditures while preserving or enhancing the quality of patient care.

Between February 2013 and June 2015, the Y–USA, in partnership with 17 local YMCAs, the Diabetes Prevention and Control Alliance, and seven other non-profit organizations, enrolled a total of 7,804 Medicare beneficiaries into the model. Enrolled beneficiaries represented a diverse geography across the eight states of Arizona, Delaware, Florida, Indiana, Minnesota, New York, Ohio, and Texas. According to the second year independent evaluation report of the Y–USA Diabetes Prevention Program model, Medicare beneficiaries demonstrated high rates of participation and sustained engagement in the Diabetes Prevention Program. Approximately 83 percent of recruited Medicare beneficiaries attended at least 4 core sessions and approximately 63 percent completed 9 or more core sessions. The first and second independent evaluation reports are available on the Innovation Center's Web site at *https://innovation.cms.gov/initiatives/Health-Care-Innovation-Awards/.*

2. Certification of the Medicare Diabetes Prevention Program (MDPP)

CMS' Office of the Actuary has determined that DPP is likely to reduce Medicare expenditures if made available to eligible Medicare beneficiaries based on historical evidence from evaluations of the Y–USA DPP and other DPPs in the CDC Diabetes Prevention Recognition Program. In addition, to evaluate the longer-term impact of the program, the CMS Actuary developed a model to estimate lifetime per participant savings of a Medicare beneficiary receiving DPP services.

The full CMS Actuary Report is available at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/ActuarialStudies/Downloads/Diabetes-Prevention-Certification-2016-03-14.pdf.*

3. Requirements for Expansion

Section 1115A(c) of the Act provides the Secretary with the authority to expand (including implementation on a nationwide basis) through rulemaking the duration and scope of a model that is being tested under section 1115A(b) of the Act if the following findings are made, taking into account the evaluation of the model under section 1115A(b)(4) of the Act: (1) The Secretary determines that the expansion is expected to either reduce spending without reducing quality of care or improve the quality of patient care without increasing spending; (2) the CMS Chief Actuary certifies that the expansion would reduce (or would not result in any increase in) net program spending; and (3) the Secretary determines that the expansion would not deny or limit the coverage or provision of benefits.

- *Improved Quality of Care without Increased Spending:* Weight loss is a key indicator of success among persons enrolled in a DPP. According to the second year independent evaluation of the Y–USA DPP HCIA project, those beneficiaries who attended at least one core session lost an average of 7.6 pounds while beneficiaries who attended at least four core sessions lost an average of 9 pounds. BMI was reduced from 32.9 to 31.5 among Medicare beneficiaries that attended at least four core sessions. Based on these findings and results from other DPP evaluations demonstrating the effectiveness of the program in preventing diabetes onset, the Secretary determined that expansion of the DPP will reduce spending and improve the quality of care.
- *Impact on Medicare Spending:* The CMS Chief Actuary has certified that expansion of the DPP would not result in an increase of Medicare spending.
- *No Alteration in Coverage or Provision of Benefits:* The DPP, if implemented in Medicare, would provide services in addition to existing Medicare services, and beneficiaries receiving DPP services would retain all benefits covered in traditional Medicare. Therefore, the Secretary has determined that expansion of DPP would not deny or limit the coverage or provision of Medicare benefits for Medicare beneficiaries.

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[9] Centers for Medicare and Medicaid Services. Chronic Conditions among Medicare Beneficiaries, Chartbook, 2012 Edition. Baltimore, MD. 2012.

[10] Boyle, J.P., Thompson, T.J., Gregg, E.W., Barker, L.E., & Williamson, D.F. (2010). Projection of the year 2050 burden of diabetes in the US adult population: Dynamic modeling of incidence, mortality, and prediabetes prevalence. Popul Health Metr, 8(1), 29.

[11] Zhang, X., Gregg, E.W., Williamson, D.F., Barker, L.E., Thomas, W., Bullard, K.M., & Albright, A.L. (2010). A1C level and future risk of diabetes: a systematic review. Diabetes Care, 33(7), 1665–1673.

4. Proposed Expansion of Medicare Diabetes Prevention Program

We propose to expand the duration and scope of the DPP model test by expanding DPP under section 1115A(c) of the Act, and we propose to refer to this expanded model as the Medicare Diabetes Prevention Program (MDPP). In this section of this proposed rule, we propose a basic framework for the MDPP. If finalized, we will engage in additional rulemaking, likely within the next year, to establish specific requirements of the MDPP. We seek comment on all of the proposals below and on any other policy or operational issues that need to be considered in implementing this expansion. The MDPP will become effective January 1, 2018.

- *MDPP as an "Additional Preventive Service" under section 1861(ddd) of the Act: CMS Authority to to Designate MDPP as an "Additional Preventive Service":* We propose to designate MDPP services as "additional preventive services" available under Medicare Part B. Section 1861(ddd) defines "additional preventive services" as services that are not preventive services or personalized prevention plan services (as those terms defined in section 1861(ddd)(3)(A) and (C)) that identify medical conditions or risk factors and that the Secretary determines are (A) reasonable and necessary for the prevention or early detection of an illness or disability; (B) recommended with a grade of A or B by the United States Preventive Services Task Force (USPSTF); and (C) appropriate for individuals entitled to benefits under Part A or enrolled in Part B.

We believe that MDPP services are generally consistent with the types of additional preventive services that are appropriate for Medicare beneficiaries. In particular, we believe that MDPP services we are proposing under the expanded MDPP model meet the requirements of section 1861(ddd)(1)(A) of the Act because they are specifically designed to prevent prediabetes from advancing into diabetes. MDPP services do not meet the requirement in section 1861(ddd)(1)(B) of the Act that they have received a recommendation with a grade of A or B by the USPSTF. However, under section 1115A(d)(1) of the Act, the Secretary has authority to waive certain requirements. We propose to use this waiver authority to waive section 1861(ddd)(1)(B) of the Act with respect to MDPP services because they have been recommended by the Community Preventive Services Task Force, which is similar to the USPSTF, and therefore a USPSTF recommendation is not necessary. We believe that MDPP services are appropriate for individuals entitled to benefits under part A or enrolled in Part B, and thus meet the requirements of section 1861(ddd)(1)(C) of the Act, because findings from the second year independent evaluation of the Y–USA DPP HCIA project and results from other DPP evaluations demonstrate effectiveness of the program in preventing diabetes onset and thus improve quality of care for Medicare beneficiaries.

Section 1861(ddd)(2) of the Act requires the Secretary to make the determinations required under section 1861(ddd)(1) of the Act using the process for making national coverage determinations (NCDs). However, we propose to waive this requirement because using the NCD process to implement the MDPP would create implementation problems, especially as this rule proposes to create a supplier class and this is an issue that the NCD process does not address.

We seek comment on these proposals.

MDPP Benefit Description: We propose MDPP to be a 12 month program using the CDC-approved DPP curriculum, consisting of 16 core sessions over 16–26 weeks and the option for monthly core maintenance sessions over 6 months thereafter if the beneficiary achieves and maintains a minimum weight loss in accordance with the CDC Diabetes Prevention Recognition Program Standards and Operating Procedures. CDC-approved DPP session curriculum requirements are detailed below.

CDC-Approved DPP Session Curriculum Requirements

During the first 6 months (weeks 1–26) of the DPP intervention, each of the 16 core sessions must address one of these curriculum topics, and all topics must be addressed by the end of the 16 sessions.

1. Welcome to the National Diabetes Prevention Program
2. Self-Monitoring Weight and Food Intake
3. Eating Less
4. Healthy Eating
5. Introduction to Physical Activity (Move Those Muscles)
6. Overcoming Barriers to Physical Activity (Being Active—A Way of Life)
7. Balancing Calorie Intake and Output
8. Environmental Cues to Eating and Physical Activity
9. Problem Solving
10. Strategies for Healthy Eating Out
11. Reversing Negative Thoughts
12. Dealing with Slips in Lifestyle Change
13. Mixing Up Your Physical Activity: Aerobic Fitness
14. Social Cues
15. Managing Stress
16. Staying Motivated, Program Wrap Up

The last 6 months (weeks 27–52) of the DPP 12-month intervention must include at least one core maintenance session delivered in each of the 6 months (for a minimum of six sessions), and all core maintenance sessions must address different topics.

1. Welcome to the Second Phase of the Program
2. Healthy Eating: Taking It One Meal at a Time
3. Making Active Choices
4. Balance Your Thoughts for Long-Term Maintenance
5. Healthy Eating With Variety and Balance
6. Handling Holidays, Vacations, and Special Events
7. More Volume, Fewer Calories (Adding Water Vegetables and Fiber)
8. Dietary Fats
9. Stress and Time Management
10. Healthy Cooking: Tips for Food Preparation and Recipe Modification
11. Physical Activity Barriers
12. Preventing Relapse
13. Heart Health
14. Life With Type 2 Diabetes
15. Looking Back and Looking Forward

CDC-approved curriculum can be found at *http://www.cdc.gov/diabetes/prevention/pdf/curriculum_toc.pdf.*

We propose that the MDPP expanded model will use the CDC-approved curriculum. We also propose that beneficiaries who meet the coverage criteria that we propose below would be able to enroll in the MDPP only once; however, we propose that those beneficiaries who complete the 12 month program and achieve and maintain a required minimum level of weight loss would be eligible for additional monthly maintenance sessions for as long as the weight loss is maintained. We propose that these ongoing maintenance sessions adhere to the same curriculum requirements as the core maintenance sessions. We propose to require that each MDPP session be at least an hour in duration.

We propose to describe the services that would be covered under the Medicare Diabetes Prevention Program expanded model at § 410.79. Consistent with our statutory authority, we will continue to test and evaluate the nationwide MDPP as finalized. In the future, we will assess whether the nationwide implementation of the MDPP is continuing to reduce Medicare spending without reducing quality of care or improve the quality of patient care without increasing spending, and could modify the nationwide MDPP as appropriate. We seek comment on this proposal.

- *Enrollment of New Medicare Suppliers:*

MDPP Supplier Enrollment Requirements: As of 2015, more than 800 organizations have preliminary or full recognition from the CDC Diabetes Prevention Recognition Program (DPRP) to provide DPP services. These organizations have served more than 40,000 participants. More than 60 health plans provide some coverage of DPP services.

We propose that any organization recognized by the CDC (that is, those with preliminary or full recognition) to provide DPP services would be eligible to apply for enrollment in Medicare as a supplier beginning on or after January 1, 2017. This proposal would promote timely enrollment of CDC-recognized organizations before billing begins, and would permit full implementation of the MDPP expansion by January 1, 2018. We propose that MDPP suppliers would be subject to the enrollment regulations set forth in 42 CFR part 424, subpart P. Organizations seeking to enroll in Medicare specifically to become MDPP Suppliers would be subject to screening under § 424.518. We are considering what level of application screening is most appropriate, and we are currently proposing that potential MDPP Suppliers be screened according to the high categorical risk category defined in § 424.518(c) because we acknowledge that MDPP may bring organization types that are entirely new to Medicare. We also believe that MDPP suppliers have some similarities to home health agencies because non-medical personnel may deliver MDPP services in a non-clinical setting, such as at Y–USA. We seek comments on this approach.

As suppliers, enrolled MDPP organizations would be obligated to comply with all statutes and regulations that establish generally applicable requirements for Medicare suppliers. For example, there are regulations that specify time limits for filing claims (§ 424.44), requirements to report and return overpayments (§ 401.305), and procedures for suspending, offsetting or recouping Medicare payments in certain situations (§ 405.371).

We propose that before enrolling in Medicare, DPP organizations must have either preliminary or full CDC recognition status. Organizations that apply for CDC recognition can attain preliminary CDC recognition within 1 year of applying, and full upon demonstrating program effectiveness within 24–36 months of applying. We propose that if an organization loses its CDC recognition status at any point, or withdraws from the CDC recognition program at any point, or fails to move from preliminary to full recognition within 36 months of applying for CDC recognition, the organization would be subject to revocation of its Medicare billing privileges for MDPP services as provided by 42 CFR part 424, subpart P. Under the CDC standards for recognition, an organization that loses its CDC recognition (and thus, under our proposal, would no longer be able to bill Medicare for MDPP services) must wait 12 months before reapplying for recognition. We propose that DPP organizations would be eligible to re-enroll in Medicare as an MDPP supplier if, after reapplying for CDC recognition, the organization again achieves preliminary recognition. CDC's standards for recognition as a DPP organization can be found at *http://www.cdc.gov/diabetes/prevention/pdf/dprp-standards.pdf.*

We propose to permit CDC-recognized organizations who are not already enrolled in Medicare (on the basis of being an existing Medicare provider or supplier) to apply to enroll any time on or after January 1, 2017. Existing Medicare providers and suppliers that wish to bill for MDPP services would have to inform us of that intention and satisfy all other requirements, but would not need to enroll a second time. These existing Medicare providers and suppliers would be eligible to bill for MDPP services furnished on or after January 1, 2018. We also considered an alternative approach where existing Medicare providers and suppliers would have to submit a separate enrollment application (including any applicable enrollment application fee) and be separately screened to be eligible to bill for MDPP services. We seek comments on our approach.

Requirements for MDPP Coaches: We propose to require personnel who would deliver MDPP services, referred to hereafter as "coaches", to obtain a National Provider Identifier (NPI) to help ensure the coaches meet CMS program integrity standards. We are also considering requiring that coaches enroll in the Medicare program in addition to obtaining an NPI, and we seek comment on this approach. An alternative policy we considered was to require DPP organizations to collect and submit to Medicare information on the coaches who would deliver MDPP services, which could include identifying information such as first and last name and social security number. However, we determined that doing so would require CMS implement a new process, rather than leveraging an existing process, and increase CMS use of social security numbers as a primary identifier. In addition, by requiring coaches to obtain NPIs, we align with current process for provider enrollment and program integrity efforts. We propose to require MDPP suppliers to submit the active and valid NPIs of all coaches who would furnish MDPP services on behalf of the MDPP supplier as an employee or contractor. If MDPP suppliers fail to provide active and valid NPIs of their coaches, or if the coaches fail to obtain or lose their active and valid NPIs, the MDPP supplier may be subject to compliance action or revocation of MDPP supplier status.

Revocation of MDPP billing privileges: We propose that all MDPP suppliers would be required to comply with the requirements of 42 CFR part 424. If an MDPP supplier has its Medicare enrollment revoked or deactivated for reasons independent of DPRP recognition, that supplier would lose its ability to bill Medicare for MDPP services but would not automatically lose its DPRP recognition from the CDC. We propose that existing Medicare providers and suppliers who lose CDC recognition would lose their Medicare billing privileges with respect to MDPP services, but may continue to bill for other non-MDPP Medicare services for which they are eligible to bill. We propose that MDPP Suppliers that have their Medicare billing privileges revoked or that lose billing privileges for MDPP may appeal these decisions in accordance with the procedures specified in 42 CFR part 405, subpart H, 42 CFR part 424, and 42 CFR part 498. We propose to add a new § 424.59 to our regulations to specify the suppliers who would be eligible for Medicare enrollment and billing for MDPP services. We seek comment on this proposal.

- *Expected MDPP Reimbursement:*

Expected MDPP Reimbursement Structure: We plan to reimburse for MDPP services at the times and in the amounts set forth in the Table 35, with payment tied to number of sessions attended and achievement of a minimum weight loss of 5 percent of baseline weight (body weight recorded during the beneficiary's first core session). MDPP suppliers would be required to attest to beneficiary session attendance and weight loss at the time claims are submitted to Medicare for payment. Each beneficiary's attendance must be documented through paper or electronic means and that each beneficiary's weight must be measured and recorded every MDPP session the beneficiary attends. MDPP suppliers would be required to securely maintain beneficiary attendance records and measured weights and make them available to CMS or its designee for audit at any time.

TABLE 35—DPP PAYMENT MODEL

	Payment per beneficiary (non-cumulative)
Core Sessions	
1 session attended	$25
4 sessions attended	50
9 sessions attended	100
Achievement of minimum weight loss of 5% from baseline weight	160
Achievement of advanced weight loss of 9% from baseline weight	*25
Maximum Total for Core sessions	360
Maintenance Sessions (Maximum of 6 monthly sessions over 6 months in Year 1)	
3 Maintenance sessions attended (with maintenance of minimum requiredweight loss from baseline)	45
6 Maintenance sessions attended (with maintenance of minimum required weight loss from baseline)	45
Maximum Total for Maintenance sessions	90
Maximum Total for first year	450
Maintenance Sessions After Year 1 (Minimum of 3 sessions attended per quarter/no maximum)	
3 Maintenance sessions attended plus maintenance of minimum required weight loss from baseline	45
6 Maintenance sessions attended plus maintenance of minimum required weight loss from baseline	45
9 Maintenance sessions attended plus maintenance of minimum required weight loss from baseline	45
12 Maintenance sessions attended plus maintenance of minimum required weight loss from baseline	45
Maximum Total After First Year	180

* In addition to $160 above.

Submission of Claims for MDPP Services: As Table 35 illustrates, proposed payments would be heavily weighted toward achievement of weight loss over the first 6 months, and no payments would be available after the first 6 months without achievement of the minimum weight loss. In the proposed payment structure, claims for payment would be submitted following the achievement of core session attendance, minimum weight loss, maintenance session attendance, and maintenance of minimum weight loss. For example, MDPP suppliers would not be able to submit another claim after session one until the beneficiary has completed four sessions, and maintenance sessions would not qualify for payment unless minimum weight loss is achieved and maintained. Similar value-based payments are being offered by commercial insurers and accepted by DPP organizations. We seek comment on this payment structure. We seek comment on whether to update payment rates annually through an existing fee schedule, such as the PFS, or establish a new fee schedule for MDPP suppliers.

- *IT infrastructure and capabilities:* We propose that in order to receive payment, MDPP suppliers would be required to submit claims to Medicare using standard claims forms and procedures. Claims would be submitted in batches that contain beneficiary Protected Health Information (PHI) and Personally Identifiable Information (PII), including the Health Insurance Claim Number (HICN). Most Medicare claims are submitted electronically except in limited situations. We provide a free software package called PC–ACE Pro32 that creates a patient database and allows organizations to electronically submit claims to Medicare Part A and B. We understand there are several other electronic claims submissions software packages available in the market for purchase. We encourage current and prospective DPP organizations to investigate adopting these systems to enhance the efficiency of claims submission, and we seek comment on the capacity of DPP organizations to integrate these systems into their workflows. If this provision is finalized, we would provide technical assistance to MDPP suppliers to comply with the Medicare claims submission standards. We seek comment from current and prospective DPP organizations on their ability to transmit claims to Medicare in a timely and secure manner.

We propose to require MDPP suppliers to maintain a crosswalk between the beneficiary identifiers they submit to CMS for billing purposes and the beneficiary identifiers they provide CDC for the beneficiary level-clinical data. We propose that MDPP suppliers provide this crosswalk to the CMS evaluator on a regular basis. We seek comment on this approach.

We plan to propose to require MDPP suppliers to maintain records that document the MDPP services provided to beneficiaries. We propose that these records must contain detailed documentation of the services provided, including but not limited to the beneficiary's eligibility status, sessions attended, the coach furnishing the session attended, the date and place of service of sessions attended, and weight. MDPP suppliers would be required to maintain these records within a larger medical record, or within a medical record that an MDPP supplier establishes for the purposes of administering MDPP. Consistent with the requirement in § 424.516(f) we propose that these records be retained for 7 years from the date of service and that MDPP suppliers would provide CMS or a Medicare contractor access to these records upon request. We propose to require MDPP suppliers to accurately track payments and resolve any discrepancies between claims and the beneficiary record within their medical record. We also propose that MDPP suppliers would be required to maintain and handle any beneficiary PII and PHI in compliance with HIPAA, other applicable privacy laws and CMS standards. If this provision is finalized, we intend to provide education and technical assistance to DPP organizations to mitigate the risk of data discrepancies and audits. We seek comment on our approach. We would address specific recordkeeping requirements and standards in future rulemaking.

- *MDPP Eligible beneficiaries:* We propose that coverage of MDPP services would be available for beneficiaries who meet the following criteria: (1) Are enrolled in Medicare Part B; (2) have as of the date of attendance at the first Core Session a body mass index (BMI) of at least 25 if not self-identified as Asian and a BMI of at least 23 if self-identified as Asian. The CDC standards have defined a lower BMI for Asian individuals based on data that show Asians develop abnormal glucose levels at a lower BMI; (3) have within the 12 months prior to attending the first Core Session a hemoglobin A1c test with a value between 5.7 and 6.4 percent, or a fasting plasma glucose of 110–125 mg/dL, or a 2-hour post-glucose challenge of of 140–199 mg/dL (oral glucose tolerance test). We use this definition of prediabetes instead of the definition in § 410.18 because the 2016 American Diabetes Association Standards of Care includes the use of a hemoglobin A1c test to diagnose prediabetes and the CMS actuarial certification uses the World Health Organization definition of prediabetes as a fasting plasma glucose of 110–125 mg/dL; (4) have no previous diagnosis of Type 1 or Type 2 diabetes. A beneficiary with previous diagnosis of gestational diabetes is eligible for MDPP; and (5) does not have end-stage renal disease (ESRD).

The National DPP currently allows community-referral such as by Y–USA and self-referral of patients, in addition to referral by physicians and other health care practitioners, if the patient presents DPP-qualifying blood test results that the DPP organization keeps on record. We propose to similarly permit beneficiaries who meet the proposed criteria above to obtain MDPP services by self-referral, community-referral, or health care practitioner-referral.

We propose to establish the beneficiary eligibility criteria at § 410.79. We seek comment on this proposal.

- *Program integrity:* We propose all DPP organizations that are eligible and wish to bill Medicare would enroll as MDPP suppliers, and thus would be required to comply with applicable Medicare supplier enrollment, program integrity, and payment rules. We recognize the potential for fraud and abuse by filing inaccurate claims and/or duplicative claims on beneficiaries' sessions attended or weight loss achieved. We also recognize beneficiaries may move between MDPP suppliers, and we intend to address in future rulemaking requirements to prevent duplication of a beneficiary's claims for the same services by more than one MDPP supplier. We are also concerned about the potential for beneficiary inducement or coercion and the potential program risks posed by permitting a new type of organization to receive payment from CMS for providing MDPP services. We intend to develop policies, and will propose them in future rulemaking, to mitigate these risks, and monitor the MDPP expansion to ensure MDPP suppliers meet all applicable CMS program integrity and supplier enrollment standards. We intend to develop system checks to identify where CMS may need to audit an MDPP supplier's medical records. We are considering ways CMS could cross reference the data DPP organizations are currently required to report to the CDC to identify potential discrepancies with data submitted to us. We seek comment on such approaches. Finally, MDPP suppliers would be subject to audits and reviews performed by CMS program integrity and/or review or audit contractors in addition to program-specific audits. We seek comment on these approaches and others to mitigate these risks and strategies to ensure program integrity.
- *Site of service:* Currently, CDC-recognized DPP organizations deliver DPP services in-person or virtually via a telecommunications system or other remote technology. The majority of current DPP organizations provide DPP services in-person, but an emerging body of literature supports the effectiveness of virtual sessions delivered remotely. We propose to allow MDPP suppliers to provide MDPP services via remote technologies. As part of our evaluation of the MDPP expansion, to the extent feasible, we will evaluate the effectiveness of MDPP services, particularly in relation to virtual versus in-person services, and, using the evaluation data, may modify or terminate this component of the expansion as appropriate. To permit such evaluation, we are considering specifying the nature of the virtual service and the site of the service in codes included on claims submitted for payment, as well as collecting information on the nature of the virtual service and the site of service at the beneficiary level from MDPP suppliers. We seek comment on this approach. Under this last example, MDPP suppliers would be expected to maintain this information as part of the beneficiary level cross walk discussed under the IT Infrastructure and Capabilities section of this proposed rule.

We plan to monitor administrative claims for virtual services to identify any unusual and/or adverse utilization of the DPP benefit. We seek comment on specific monitoring activities or program integrity safeguards with respect to virtual services, in addition to the time period in which such enhanced monitoring activities should occur.

We note that MDPP services provided via a telecommunications system or other remote technology will not be part of the current Medicare telehealth benefits and have no impact on how telehealth services are defined by Medicare. We recognize that the provision of MDPP services by such virtual methods may introduce additional risks for fraud and abuse, and if this proposal is finalized, we would propose specific policies in future rulemaking to mitigate these risks. We thus seek comment on whether there are quality or program integrity concerns regarding the use of virtual sessions, or whether they offer comparable or higher quality MDPP services when compared to in-person services. We seek comment on strategies to strengthen program integrity and minimize the potential for fraud and abuse in virtual sessions.

- *Learning activities:* The CDC provides technical assistance to DPP organizations recognized by the DPRP to improve performance. We intend to coordinate with CDC to supplement this technical assistance with education, training and technical assistance on data security, claims submission and medical record keeping. We seek comment on what additional technical assistance would be needed by providers and other organizations in order to expand the MDPP model.
- *Quality monitoring and reporting:* We seek comment on the quality metrics

that should be reported by MDPP suppliers in addition to the reporting elements required on Medicare claims submissions outlined above (attendance and weight loss) or by the CDC recognition program. We seek comment specifically on what quality metrics should be considered for public reporting (not for payment) to guide beneficiary choice of MDPP suppliers.

- *Timing of the MDPP expansion:* Expanding the MDPP model will be a technically and logistically complex undertaking. One option may be to expand the MDPP nationally in its first year of implementation. Another option is a "phase-in" approach, where the MDPP is expanded initially for a period of time in certain geographic markets or regions, or is furnished by a subpopulation of MDPP suppliers, with the goal of addressing technical issues prior to broader expansion. We seek comment on expanding DPP nationally, and specifically on what factors we should consider in the selection of initial MDPP suppliers.

K. Medicare Shared Savings Program

Under section 1899 of the Act, we established the Medicare Shared Savings Program (Shared Savings Program) to facilitate coordination and cooperation among providers to improve the quality of care for Medicare Fee-For-Service (FFS) beneficiaries and reduce the rate of growth in health care costs. Eligible groups of providers and suppliers, including physicians, hospitals, and other health care providers, may participate in the Shared Savings Program by forming or participating in an Accountable Care Organization (ACO). The final rule establishing the Shared Savings Program appeared in the November 2, 2011 **Federal Register** (Medicare Shared Savings Program: Accountable Care Organizations Final Rule (76 FR 67802) (November 2011 final rule)). A subsequent major update to the program rules appeared in the June 9, 2015 **Federal Register** (Medicare Shared Savings Program; Accountable Care Organizations Final Rule (80 FR 32692) (June 2015 final rule)). A final rule addressing changes related to the program's financial benchmark methodology appeared in the June 10, 2016 **Federal Register** (Medicare Program; Medicare Shared Savings Program; Accountable Care Organizations—Revised Benchmark Rebasing Methodology, Facilitating Transition to Performance-Based Risk, and Administrative Finality of Financial Calculations (81 FR 37950) (June 2016 final rule)). As noted below, we have also made use of the annual PFS rules to address quality reporting and certain other issues.

Additionally, on April 27, 2016, the Department of Health and Human Services (HHS) issued a proposed rule to implement key provisions of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) and establish a new Quality Payment Program (QPP) (Medicare Program; Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models (81 FR 28162) (QPP proposed rule)). The QPP proposed rule would establish a new program under which Medicare would reward physicians for providing high-quality care, instead of paying them only for the number of tests or procedures provided. The QPP proposed rule addresses issues related to APMs, such as the Medicare Shared Savings Program, and issues related to reporting for purposes of MIPS by eligible clinicians (ECs) that are participating in APMs.

Our intent in this proposed rule is to propose further refinements to the Shared Savings Program rules, and we have identified several policies that we propose to update or revise. First, we discuss and propose policies related to ACO quality reporting including proposing changes to the quality measures used to assess ACO quality performance, changes in the methodology used in our quality validation audits and the way in which the results of these audits may affect an ACO's sharing rate, various issues related to alignment with policies proposed in the QPP proposed rule, and revisions related to the terminology used in quality assessment such as "quality performance standard" and "minimum attainment level." We are also proposing conforming changes to our regulatory text. Next, we address several issues unrelated to quality reporting and assessment. Specifically, we propose to implement a process by which beneficiaries may voluntarily align with an ACO by designating an ACO professional as responsible for their overall care. We also propose to introduce beneficiary protections related to use of the SNF 3-Day Waiver. Finally, we are proposing to make technical changes to certain rules related to merged and acquired TINs and the minimum savings rate (MSR) and minimum loss rate (MLR) that would be used during financial reconciliation for ACOs that fall below 5,000 assigned beneficiaries.

1. ACO Quality Reporting

Section 1899(b)(3)(A) of the Act requires the Secretary to determine appropriate measures to assess the quality of care furnished by ACOs, such as measures of clinical processes and outcomes; patient, and, wherever practicable, caregiver experience of care; and utilization such as rates of hospital admission for ambulatory sensitive conditions. Section 1899(b)(3)(B) of the Act requires ACOs to submit data in a form and manner specified by the Secretary on measures that the Secretary determines necessary for ACOs to report to evaluate the quality of care furnished by ACOs. Section 1899(b)(3)(C) of the Act requires the Secretary to establish quality performance standards to assess the quality of care furnished by ACOs, and to seek to improve the quality of care furnished by ACOs over time by specifying higher standards, new measures, or both for the purposes of assessing the quality of care. Additionally, section 1899(b)(3)(D) of the Act gives the Secretary authority to incorporate reporting requirements and incentive payments related to the PQRS, EHR Incentive Program and other similar initiatives under section 1848 of the Act. Finally, section 1899(d)(1)(A) of the Act states that an ACO is eligible to receive payment for shared savings, if they are generated, only after meeting the quality performance standards established by the Secretary.

In the November 2011 final rule and recent CY PFS final rules with comment period (77 FR 69301 through 69304; 78 FR 74757 through 74764; 79 FR 67907 through 67931; and 80 FR 71263 through 712710), we have established the quality performance standard that ACOs must meet to be eligible to share in savings that are generated. For example, in the CY 2015 PFS final rule with comment period, we made a number of updates to the quality requirements within the program, such as updates to the quality measure set, the addition of a quality improvement reward, and the establishment of benchmarks for 2 years. We made further updates to the quality measure set, established policies to address outdated measures, and made conforming changes to align with PQRS in the CY 2016 PFS final rule with comment period. Through these previous rulemakings, we have worked to improve the alignment of quality performance measures, submission methods, and incentives under the Shared Savings Program and PQRS. Currently, eligible professionals billing through the TIN of an ACO participant may avoid the downward PQRS payment adjustment when the ACO satisfactorily reports the ACO GPRO measures on their behalf using the CMS web interface.

We are proposing several changes and other revisions to our policies related to the quality measures and quality performance standard in this rule, including the following:

- Changes to the measure set used in establishing the quality performance standard;
- Changes to the methodology used to validate quality data submitted by the ACO along with penalties that may apply if the audit match rate is less than 90 percent;
- Revisions to the use of the terms "quality performance standard" and "minimum attainment level" in the regulation text;
- Revisions related to use of flat percentages to establish quality benchmarks; and
- Alignment with policies proposed in the QPP proposed rule.

a. Changes to the Quality Measure Set Used in Establishing the Quality Performance Standard

(1) Background

Section 1899(b)(3)(C) of the Act states that the Secretary shall establish quality performance standards to assess the quality of care furnished by ACOs and seek to improve the quality of care furnished by ACOs over time by specifying higher standards, new measures, or both. In the November 2011 final rule, we established a quality performance standard consisting of 33 measures across four domains, including patient experience of care, care coordination/patient safety, preventive health, and at-risk population. In subsequent PFS final rules with comment period, we made a number of updates to the set of measures that make up the quality performance standard. For example, in the CY 2015 PFS final rule with comment period, we added new measures that ACOs must report, retired measures that no longer aligned with updated clinical guidelines, reduced the sample size for measures reported through the CMS web interface, established a schedule for the phase in of new quality measures, and established an additional reward for quality improvement. The revisions to the measures set made in the CY 2016 PFS final rule with comment period, resulted in a net increase in the quality measure set from 33 measure to 34 measures.

Quality measures are submitted by the ACO through the CMS web interface, calculated by CMS from administrative and claims data, and collected via a patient experience of care survey based on the Clinician and Group Consumer Assessment of Healthcare Providers and Systems (CG–CAHPS) survey. The CAHPS for ACOs patient experience of care survey used for the Shared Savings Program includes the core CG–CAHPS modules, as well as some additional modules. The measures collected through the CMS web interface are also used to determine whether eligible professionals participating in an ACO avoid the PQRS and automatic Physician Value Modifier (VM) payment adjustments for 2015 and subsequent years. Currently, eligible professionals billing through the TIN of an ACO participant may avoid the downward PQRS payment adjustment when the ACO satisfactorily reports all of the ACO GPRO measures on their behalf using the CMS web interface. Beginning with the 2017 VM, ACO performance on the CMS web interface measures and all cause readmission measure will be used in calculating the quality component of the VM for groups and solo practitioners participating within an ACO (79 FR 67941 through 67947).

As we previously stated (76 FR 67872), our principal goal in selecting quality measures for ACOs has been to identify measures of success in the delivery of high-quality health care at the individual and population levels with a focus on outcomes. We believe endorsed measures have been tested, validated, and clinically accepted, and therefore, when selecting the original 33 measures, we had a preference for NQF-endorsed measures. However, the statute does not limit us to using endorsed measures in the Shared Savings Program. As a result, we have also exercised our discretion to include certain measures that we believe to be high impact but that are not currently endorsed, including for example, ACO#11, which is currently titled Percent of PCPs Who Successfully Meet Meaningful Use Requirements.

In selecting the original measure set, we balanced a wide variety of important considerations. Our measure selection emphasized prevention and management of chronic diseases that have a high impact on Medicare FFS beneficiaries, such as heart disease, diabetes mellitus, and chronic obstructive pulmonary disease. We believed that the quality measures used in the Shared Savings Program should be tested, evidence-based, target conditions of high cost and high prevalence in the Medicare FFS population, reflect priorities of the National Quality Strategy, address the continuum of care to reflect the requirement that ACOs accept accountability for their patient populations, and align with existing quality programs and value-based purchasing initiatives.

In the CY 2015 PFS final rule with comment period we finalized a number of changes to the quality measures used in establishing the quality performance standard to better align with PQRS, retire measures that no longer align with updated clinical practice, and add new outcome measures that support the CMS Quality Strategy and National Quality Strategy goals. In the CY 2016 PFS final rule with comment period, in modifying the measures set we sought to include both process and outcome measures, including patient experience of care (80 FR 71263 through 71268). We believe it is important to retain a combination of both process and outcomes measures because ACOs are charged with improving and coordinating care and delivering high quality care, but also need time to form, acquire infrastructure and develop clinical care processes. However, as other CMS quality reporting programs, such as PQRS, move to more outcomes-based measures and fewer process measures over time, we have indicated that we might also revise the quality performance standard for the Shared Savings Program to incorporate more outcomes-based measures and fewer process measures over time.

We are also continuing to work with the measures community to ensure that the specifications for the measures used under the Shared Savings Program are up-to-date and reduce reporting burden. We believe that it is important to balance the timing of the release of specifications so they are as up-to-date as possible, while also giving ACOs sufficient time to review specifications. Our intention is to issue the specifications annually, prior to the start of the reporting period for which they will apply.

The Core Quality Measures Collaborative was formed in 2014, as a collaboration between CMS, providers, and other stakeholders, with the goal of aligning quality measures for reporting across public and private stakeholders in order to reduce provider reporting burden. On February 16, 2016, the Core Quality Measures Collaborative recommended a core quality measure set that aligns and simplifies quality reporting across multiple payers (*https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2016-Press-releases-items/2016-02-16.html*) and made specific recommendations for ACOs (*https://*

www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/Downloads/ACO-and-PCMH-Primary-Care-Measures.pdf). We proposed to integrate several recommendations made by the Core Quality Measures Collaborative into the CMS web interface as part of the QPP proposed rule (81 FR 28399). Groups that are eligible to report using the CMS web interface for purposes of reporting quality measures to CMS for various quality reporting initiatives such as PQRS, the Shared Savings Program are required to report on all measures included in the CMS web interface. In addition, in the QPP proposed rule, we proposed that groups would also be required to report on all CMS web interface measures.

(2) Proposals

In efforts to continue to align with other CMS initiatives and reduce provider confusion and the burden of reporting, we propose modifications to the quality measure set that an ACO is required to report. Specifically, to align the Shared Savings Program quality measure set with the measures recommended by the Core Quality Measures Collaborative and proposed for reporting through the CMS web interface under the QPP proposed rule, we propose to add, and in some cases to replace, existing quality measures with the following:

- *ACO–12 Medication Reconciliation Post-Discharge (NQF #0097).* This measure addresses adverse drug events (ADEs) through medication reconciliation, which is an important aspect of care coordination. According to HHS' Agency for Healthcare Research and Quality (AHRQ), ADEs account for nearly 700,000 emergency department visits and 100,000 hospitalizations each year.[12] The ACO–12 Medication Reconciliation measure was previously in the Shared Savings Program measure set, however, it was replaced with ACO–39, Documentation of Current Medications in the Medical Record (79 FR 67912 through 67914). The Core Quality Measures Collaborative, in coordination with providers and stakeholders, determined the original Medication Reconciliation measure would be more appropriate for alignment across quality reporting initiatives. Based on this recommendation, we have proposed to require reporting of the measure through the CMS web interface in the QPP proposed rule (81 FR 28403). In an effort to align with the QPP proposals, we therefore propose to replace the Documentation of Current Medications in the Medical Record measure (ACO–39) by reintroducing Medication Reconciliation (ACO–12) in the Care Coordination/Patient Safety domain. We note that in accordance with our policy for newly introduced measures, this measure would phase into pay for performance after two years as pay for reporting, unless the measure has been finalized only as pay for reporting. We propose to phase the measure into pay for performance in accordance with the schedule outlined in Table 36 which is consistent with the original phase in schedule for the measure under the 2011 final rule.

- *ACO–44 Use of Imaging Studies for Low Back Pain (NQF #0052).* Imaging utilization is an important area for quality measurement, because of the wide use of imaging services. This measure reports the percentage of patients with a primary diagnosis of low back pain that did not have an imaging study (for example, MRI, CT scan) within 28 days of the diagnosis. (A higher score indicates higher performance). The Use of Imaging Studies for Low Back Pain quality measure is specified for patients 18–50 years of age. This age range could result in smaller case sizes for some ACOs; however, it addresses the appropriate use of imaging for low back pain, which is a condition that affects a high volume of adults in the United States. We propose adding this measure in the Care Coordination/Patient Safety domain to address a gap in measures related to resource utilization and align with the ACO measures recommended by the Core Quality Measures Collaborative core measure set (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/Downloads/ACO-and-PCMH-Primary-Care-Measures.pdf*). We note the measure is also proposed in the QPP proposed rule for measuring the quality of care furnished by individual and specialty ECs (81 FR 28399 and 28460 Tables A and E). If finalized, the measure would not be reported through the CMS web interface. Instead, it would be calculated using Medicare claims data without any additional provider reporting requirement. We note that in accordance with our policy for newly introduced measures, this measure would be designated as pay for reporting in 2017 and 2018, and then phase into pay for performance. We propose to phase the measure into pay for performance in accordance with the schedule outlined in Table 36. Specifically, following the initial 2 years of pay for reporting, we propose to phase in the measure to pay for performance starting with PY2 of an ACO's first agreement period. We believe this is reasonable because there is no reporting burden on the part of the ACO and because many stakeholders have some familiarity with similar claims-based outcomes measures. However, given the possible small case sizes due to the measure specifications, we seek comment on if this measure should be phased in to pay for performance or whether it should remain pay for reporting for all three performance years.

By aligning the Shared Savings Program measures with the Core Quality Measures Collaborative recommendations and proposals under the QPP proposed rule, we hope to reduce the burden of provider data collection and reporting of measures that do not align across public and private quality reporting initiatives. Therefore, we propose to retire or replace the following measures in order to reduce provider reporting burden by reducing the number of measures that must be reported and because these measures do not align with the core measure set recommendations from the Core Quality Measures Collaborative and the measures that we proposed for reporting through the CMS web interface in the QPP proposed rule:

- ACO–39 Documentation of Current Medications in the Medical Record.
- ACO–21 Preventive Care and Screening: Screening for High Blood Pressure and Follow-up Documented.
- ACO–31 Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD).
- ACO–33 Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy—for patients with CAD and Diabetes or Left Ventricular Systolic Dysfunction (LVEF <40%).

In addition to our proposals above to modify the quality measure set to align with the Core Quality Measures Collaborative and the proposed modifications to the measures reported through the CMS web interface under the QPP proposed rule, we propose a few additional modifications as follows:

First, we propose to retire the two AHRQ Ambulatory Sensitive Conditions Admission measures (ACO–9 and ACO–10). Although ACO–9 and ACO–10 address admissions for patients with heart failure, chronic obstructive pulmonary disease (COPD), and asthma, we introduced two all-cause, unplanned admission measures for heart failure and multiple chronic conditions (ACO–37 and ACO–38, respectively) in the 2015 PFS final rule (79 FR 67911–67912). We believe ACO–37 and ACO–38 report on a similar population with similar conditions as ACO–9 and ACO–10. Therefore, in order to continue our efforts to reduce redundancies within the Shared Savings Program measure set, we propose to remove ACO–9 and ACO–10 from the measure set.

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[12] "Medication Errors." AHRQ. *https://psnet.ahrq.gov/primers/primer/23/medication-errors.*

Second, while we are proposing above to remove ACO–9 and ACO–10, we continue to believe AHRQ's Prevention Quality Indicator (PQI) measures are important because they report on inpatient hospital admissions of patients with clinical conditions that could potentially be prevented with high-quality outpatient care. Coordination of patient care and patient access to primary care services can often prevent complications or hospital admissions. AHRQ's PQI #91 *Ambulatory Sensitive Condition Acute Composite* is a composite measure, currently used in the Physician Value-Based Payment Modifier, which includes PQIs reporting on admissions related to dehydration, bacterial pneumonia, and urinary tract infections (PQIs #10, 11, and 12). Dehydration, bacterial pneumonia, and urinary tract infection admissions may occur as a result of inadequate access to ambulatory care or poorly coordinated ambulatory care. As a result, we propose adding *ACO–43 Ambulatory Sensitive Condition Acute Composite (AHRQ PQI #91)* to the Care Coordination/Patient Safety domain. The measure will be risk-adjusted for demographic variables and comorbidities. In accordance with our policy for newly introduced measures, we propose that this measure be pay for reporting for two years, and then phase into pay for performance in accordance with the schedule outlined in Table 36.

Table 36 lists the Shared Savings Program quality measure set and summarizes our proposed measure changes, which will be used to assess quality performance starting with the 2017 performance year. We note that, consistent with our rules at § 425.502(a)(4), all newly introduced measures are set at the level of complete and accurate reporting for the first two reporting periods for which reporting of the measures is required. Therefore, the proposed new measures discussed above, including the Medication Reconciliation measure, would be pay for reporting for the 2017 and 2018 performance years. Beginning in the 2019 performance year, these quality measures will be assessed according to the phase-in schedule noted in Table 36.

As a result of these proposed measure changes, each of the four domains will include the following number of quality measures (See Table 37 for details.):

- Patient/Caregiver Experience of Care—8 measures
- Care Coordination/Patient Safety—10 measures
- Preventive Health—8 measures
- At Risk Population—5 measures (3 individual measures and a 2-component diabetes composite measure)

Table 37 provides a summary of the number of measures by domain and the total points and domain weights that would be used for scoring purposes with the proposed changes to the quality measures.

TABLE 36—MEASURES FOR USE IN THE ESTABLISHING QUALITY PERFORMANCE STANDARD THAT ACOS MUST MEET FOR SHARED SAVINGS

Domain	ACO measure #	Measure title	New measure	NQF #/measure steward	Method of data submission	Pay for performance phase in R—reporting P—performance		
						PY1	PY2	PY3
AIM: Better Care for Individuals								
Patient/Caregiver Experience	ACO–1	CAHPS: Getting Timely Care, Appointments, and Information.		N#0005 AHRQ	Survey	R	P	P
	ACO–2	CAHPS: How Well Your Providers Communicate. [13]		NQF #0005 AHRQ.	Survey	R	P	P
	ACO–3	CAHPS: Patients' Rating of Provider. [2]		NQF #0005 AHRQ.	Survey	R	P	P
	ACO–4	CAHPS: Access to Specialists		NQF #N/A CMS/AHRQ.	Survey	R	P	P
	ACO–5	CAHPS: Health Promotion and Education.		NQF #N/A CMS/AHRQ.	Survey	R	P	P
	ACO–6	CAHPS: Shared Decision Making.		NQF #N/A CMS/AHRQ.	Survey	R	P	P
	ACO–7	CAHPS: Health Status/Functional Status.		NQF #N/A CMS/AHRQ.	Survey	R	R	R
	ACO–34	CAHPS: Stewardship of Patient Resources.		NQF #N/A CMS/AHRQ.	Survey	R	P	P
Care Coordination/Patient Safety.	ACO–8	Risk-Standardized, All Condition Readmission.		Adapted NQF #1789 CMS.	Claims	R	R	P
	ACO–35	Skilled Nursing Facility 30-Day All-Cause Readmission Measure (SNFRM).		Adapted NQF #2510 CMS.	Claims	R	R	P
	ACO–36	All-Cause Unplanned Admissions for Patients with Diabetes.		NQF #TBD CMS.	Claims	R	R	P
	ACO–37	All-Cause Unplanned Admissions for Patients with Heart Failure.		NQF #TBD CMS.	Claims	R	R	P
	ACO–38	All-Cause Unplanned Admissions for Patients with Multiple Chronic Conditions.		NQF #TBD CMS.	Claims	R	R	P

TABLE 36—MEASURES FOR USE IN THE ESTABLISHING QUALITY PERFORMANCE STANDARD THAT ACOS MUST MEET FOR SHARED SAVINGS—Continued

Domain	ACO measure #	Measure title	New measure	NQF #/measure steward	Method of data submission	Pay for performance phase in R—reporting P—performance		
						PY1	PY2	PY3
	ACO–43	Ambulatory Sensitive Condition Acute Composite (AHRQ Prevention Quality Indicator (PQI) #91).	X	AHRQ	Claims	R	P	P
	ACO–11	Use of certified EHR technology.	X	NQF #N/A CMS.	As proposed in the QPP proposed rule.	R	P	P
	ACO–12	Medication Reconciliation Post-Discharge.	X	NQF #0097 CMS.	CMS Web Interface.	R	P	P
	ACO–13	Falls: Screening for Future Fall Risk.		NQF #0101 NCQA.	CMS Web Interface.	R	P	P
	ACO–44	Use of Imaging Studies for Low Back Pain.	X	NQF #0052 NCQA.	Claims	R	P	P
AIM: Better Health for Populations								
Preventive Health	ACO–14	Preventive Care and Screening: Influenza Immunization.		NQF #0041 AMA–PCPI.	CMS Web Interface.	R	P	P
	ACO–15	Pneumonia Vaccination Status for Older Adults.		NQF #0043 NCQA.	CMS Web Interface.	R	P	P
	ACO–16	Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow Up.		NQF #0421 CMS.	CMS Web Interface.	R	P	P
	ACO–17	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention.		NQF #0028 AMA–PCPI.	CMS Web Interface.	R	P	P
	ACO–18	Preventive Care and Screening: Screening for Clinical Depression and Follow-up Plan.		NQF #0418 CMS.	CMS Web Interface.	R	P	P
	ACO–19	Colorectal Cancer Screening		NQF #0034 NCQA.	CMS Web Interface.	R	R	P
	ACO–20	Breast Cancer Screening		NQF #2372 NCQA.	CMS Web Interface.	R	R	P
	ACO–42	Statin Therapy for the Prevention and Treatment of Cardiovascular Disease.		NQF #N/A CMS.	CMS Web Interface.	R	R	R
Clinical Care for At Risk Population—Depression.	ACO–40	Depression Remission at Twelve Months.		NQF #0710 MNCM.	CMS Web Interface.	R	R	R
Clinical Care for At Risk Population—Diabetes.	ACO–27	Diabetes Composite (All or Nothing Scoring): ACO–27: Diabetes Mellitus: Hemoglobin A1c Poor Control.		NQF #0059 NCQA (individual component).	CMS Web Interface.	R	P	P
	ACO–41	ACO–41: Diabetes: Eye Exam		NQF #0055 NCQA (individual component).	CMS Web Interface.	R	P	P
Clinical Care for At Risk Population—Hypertension.	ACO–28	Hypertension (HTN): Controlling High Blood Pressure.		NQF #0018 NCQA.	CMS Web Interface.	R	P	P
Clinical Care for At Risk Population—Ischemic Vascular Disease.	ACO–30	Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic.		NQF #0068 NCQA.	CMS Web Interface.	R	P	P

TABLE 37—NUMBER OF MEASURES AND TOTAL POINTS FOR EACH DOMAIN WITHIN THE QUALITY PERFORMANCE STANDARD

Domain	Number of individual measures	Total measures for scoring purposes	Total possible points	Domain weight (percent)
Patient/Caregiver Experience	8	8 individual survey module measures	16	25
Care Coordination/Patient Safety	10	10 measures, including double-scored EHR measure.	22	25
Preventive Health	8	8 measures	16	25

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[13] The quality measure title has been updated to "Providers" and is not only referencing "Doctors."

TABLE 37—NUMBER OF MEASURES AND TOTAL POINTS FOR EACH DOMAIN WITHIN THE QUALITY PERFORMANCE STANDARD—Continued

Domain	Number of individual measures	Total measures for scoring purposes	Total possible points	Domain weight (percent)
At-Risk Population	5	3 individual measures, plus a 2-component diabetes composite measure that is scored as one measure.	8	25
Total in all Domains	31	30	62	100

b. Improving the Process Used To Validate ACO Quality Data Reporting

(1) Background

In the November 2011 final rule, we finalized a proposal to retain the right to validate the data ACOs enter into the Web Interface (76 FR 67893 through 67894). This validation process, referred to as the Quality Measures Validation audit, was based on the process used in Phase I of the Physician Group Practice (PGP) demonstration. The policy was finalized at § 425.500(e). In this audit process, CMS selects a subset of Web Interface measures, and selects a random sample of 30 confirmed and completely reported beneficiaries for each measure in the subset. The ACO provides medical records to support the data reported in the Web Interface for those beneficiaries. A measure-specific audit performance rate is then calculated using a multi-phased audit process:

- *Phase 1:* Eight randomly selected medical records for each audited measure are reviewed to determine if the medical record documentation supports what was reported (that is, a match). If all records reviewed support what was reported, the audit ends. If any records do not support what was reported (that is, a mismatch), the audit process continues in a second phase for any measure with a mismatch identified.
- *Phase 2:* The remaining 22 medical records are reviewed for any measure that had a mismatch identified in Phase 1. If less than 90 percent of the medical records provided for a measure support what was reported, the audit process continues to Phase 3.
- *Phase 3:* For each measure with a match rate less than 90 percent, CMS provides education to the ACO about how to correct reporting and the ACO is given an opportunity to resubmit the measure(s) in question.

If at the conclusion of the third phase there is a discrepancy greater than 10 percent between the quality data reported and the medical records provided during the audit, the ACO will not be given credit for meeting the quality target for any measure(s) for which the mismatch rate exists.

Since publication of the initial program rules in 2011, we have gained experience in conducting audits and believe that certain modifications to our rules should be made in order to increase the statistical rigor of the audit methodology, streamline audit operations, and more closely align the Quality Measures Validation audit used in Shared Savings Program audits with other CMS quality program audits including those performed in the Physician Quality Reporting Program and the Hospital Inpatient and Outpatient Quality Reporting programs. Below, we propose four improvements to the previously described process. The proposed changes address the number of records to be reviewed per measure, the number of audit phases, the calculation of an audit match rate and the consequences if the audit match rate falls below 90 percent.

(2) Proposals

First, we propose to increase the number of records audited per measure to achieve a high level of confidence that the true audit match rate is within 5 percentage points of the calculated result. The November 2011 final rule indicated that CMS would review as few as 8 records (Phase 1 only) or as many as 30 records (Phase 1 and 2) per audited measure. With this phased methodology, the total number of records reviewed for each ACO varies (range of 40 to 150 records per audited ACO during the Performance Year 2014 audit). A sample size analysis found that the number of reviewed records needs to increase in order to provide the desired high level of confidence that the audited sample is representative of the ACO's quality reporting performance. We note that the precise number of records requested for review would vary, depending on the desired confidence level, the number of measures audited, and the expected match rate. Therefore, we are not proposing a specific number of records that would be requested for purposes of ACO quality validation audits in the future. However, based on an analysis using the poorest expected match rate, the highest degree of confidence and an estimated number of measures to be audited, we do not anticipate more than 50 records will be requested per audited measure.

Second, we propose to modify our regulations in order to conduct the quality validation audit in a single step rather than the current multi-phased process described at § 425.500(e)(2). We propose to use a more streamlined approach in which all records selected for audit are reviewed in a single step and some activities currently conducted in phase 3 would be removed from the audit process entirely while others would instead be addressed at the conclusion of the audit. During the proposed single step, we would review all submitted medical records and calculate the match rate. The education we currently provide to ACOs and the opportunity for ACOs to explain the mismatches that occur in Phase 3 of the current process would continue, but would occur at the conclusion of the audit. Under this proposal, there would not be an the opportunity for ACOs to correct and resubmit data for any measure with a >10 percent mismatch because we have learned through our experience with program operations that resubmission of CMS Web Interface measure data after the close of the CMS Web Interface is not feasible. Instead, we propose that an ACO's quality score would be affected by an audit failure as described below, without requiring re-opening of the CMS Web Interface. This single step process would allow us to maintain the desired level of confidence that the true audit match rate is within 5 percentage points of the calculated result and to complete the audit in a more timely manner. Therefore, we propose to remove the provision at § 425.500(e)(2) that requires 3 phases of medical record review. In so doing, we propose to redesignate § 425.500(e)(3) as § 425.500(e)(2).

Third, we propose to revise § 425.500(e)(3) in order to provide for an assessment of the ACO's overall audit match rate across all measures, instead of assessing the ACO's audit mismatch rate at the measure level. Specifically, we propose to calculate an overall audit match rate which would be derived by dividing the total number of audited records that match the information reported in the Web Interface by the total number of records audited. This is a change from the current audit performance calculation methodology, which calculates a measure specific mismatch rate. We believe that making this change is necessary to minimize the number of records that must be requested in order to achieve the desired level of statistical certainty as described in our first proposal in this section. Our analysis suggests that we would have to request a much larger number of records (approximately 200 per measure) from the ACO during a quality validation audit of individual measures to achieve a 90 percent confidence interval for each measure. In addition, combining all records to calculate an overall audit match rate is less subject to variability based on the specific subset of measures chosen for audit each year and better aligns with the methodology used by other CMS quality program audits.

Fourth, we propose to revise the redesignated provision at § 425.500(e)(2), to indicate that if an ACO fails the audit (that is, has an overall audit match rate of less than 90 percent), the ACO's overall quality score would be adjusted proportional to its audit performance. Currently, our regulation at § 425.500(e)(3) states that if, at the conclusion of the audit process there is a discrepancy greater than 10 percent between the quality data reported and the medical records provided, the ACO will not be given credit for meeting the quality target for any measures for which this mismatch rate exists. In light of our proposed modifications to the quality validation audit process above in which we propose to assess and validate the ACO's performance overall rather than the ACO's performance on each measure, we believe a modification to this requirement is necessary to reflect an overall adjustment. Therefore, we propose to modify the provision at newly redesignated § 425.500(e)(2) to state that if an ACO fails the audit (that is, has an audit match rate of less than 90 percent), the ACO's overall quality score will be adjusted proportional to the ACO's audit performance. The audit-adjusted quality score will be calculated by multiplying the ACO's overall quality score by the ACO's audit match rate. For example, if an ACO's quality score is 75 percent and the ACO's audit match rate is 80 percent, the ACO's audit-adjusted quality score is 60 percent. The audit-adjusted quality score would be the quality score that is used to determine the percentage of any earned savings that the ACO may share or the percentage of any losses for which the ACO is accountable.

Finally, we propose to add a new requirement at § 425.500(e)(3) that in addition to the adjustment in the ACO's overall quality score, any ACO that has an audit match rate of less than 90 percent, may be required to submit a corrective action plan (CAP) under § 425.216 for CMS approval. In the CAP, the ACO may be required to explain the cause of its audit performance and how it plans to improve the accuracy of its quality reporting in the future. In addition, CMS maintains the right, as described in § 425.500(f), to terminate or impose other sanctions on any ACO that does not report quality data accurately, completely or timely.

We invite comment on the proposed improvements to the process used to validate ACO quality data reporting.

c. Technical Changes Related to Quality Reporting Requirements

The Shared Savings Program quality reporting rules were originally established through rulemaking in the November 2011 final rule. In this section, we make several proposals regarding the quality performance standard that an ACO must meet to be eligible to share in savings. Part of the determination of whether an ACO has met the quality reporting standard in each year is dependent on the ACO meeting the minimum attainment level for certain measures. We discuss how the "minimum attainment" requirement has been implemented to date and propose a modification that we believe is more consistent with our policies for assessing an ACO's performance over time. Finally, we propose to move references to compliance actions from § 425.502(d)(2)(ii) to a more appropriate provision at § 425.316(c).

First, we propose to make technical revisions to ensure stakeholder understanding of the definition of the quality performance standard. The quality performance standard is established under Subpart F for each performance year (§ 425.502(a)). For the first performance year of an ACO's first agreement period, the quality performance standard is defined as complete and accurate reporting of all quality measures. For each subsequent performance year, quality measures phase in to pay for performance, and although the ACO must continue to report all measures completely and accurately, the ACO will also be assessed on performance based on the quality performance benchmark and minimum attainment level of certain measures that are designated as pay for performance. The quality performance standard that applies to an ACO's final year in its first agreement period also applies to each year of an ACO's subsequent agreement period (§ 425.502(a)(3)) (79 FR 67925 through 67926). ACOs must meet or exceed the minimum quality performance standard in a given performance year to be eligible to receive payments for shared savings (§ 425.100(b)). Conversely, failure to meet the quality performance standard in a given performance year makes ACOs ineligible to share in savings, even if generated, and such ACOs may be subject to compliance actions.

Our intent in the November 2011 final rule was to establish a single quality performance standard that would apply for each performance year in which an ACO participates in the program. Because the quality performance standard changes, depending on the performance year, the ACO may be subject to multiple quality performance standards over the course of its 3-year agreement period. We recognize that some of the language used in subsequent revisions to our regulations may have generated some confusion related to this issue. For example, as explained above, the quality performance standard refers to the overall standard the ACO must meet, however, in § 425.502(a)(4), we state that the quality performance standard for a newly introduced measure is set at the level of complete and accurate reporting for the first two reporting periods for which reporting of the measure is required. We wish to clarify that while there are certain standards that must be met for each measure or in each domain, there is one overall quality performance standard that must be met in each performance year by an ACO. We propose to make conforming changes to the regulations text to remove references to the quality performance standard in contexts where it does not appear to apply to the overall quality performance standard (see § 425.316(c)(2), § 425.502(a)(4), and § 425.502(d)(1)). We do not believe that modifications necessarily must be made to the regulations text in all instances where there is a reference to multiple quality performance standards, however, because we recognize that the quality performance standard varies depending on the performance year in question as indicated at § 425.502(a)(1)–(3) or, for example, where we refer to ACOs having to meet quality performance standards to be eligible to share in savings (§ 425.100(b)). Therefore, we propose to retain certain references to multiple quality performance standards, such as the one found in § 425.100(b), because we believe the use of the plural is appropriate in certain contexts.

Second, we wish to address the concept of the minimum attainment level and its use in determining whether an ACO has met the quality performance standard. As noted above, beginning in the second year of an ACO's first agreement period, the quality performance standard is met by complete and accurate reporting on all measures, but also includes meeting the minimum attainment level on "certain" measures. As provided at § 425.502(b)(1), we designate a performance benchmark and minimum attainment level for each measure. Pursuant to § 425.502(b)(3), the minimum attainment level is set at 30 percent or the 30th percentile of the performance benchmark. In § 425.502(c)(1) through (c)(2), we state that performance below the minimum attainment level for a measure will receive zero points for that measure and performance equal to or greater than the minimum attainment level for a measure will receive points on a sliding scale based on the level of performance. Finally, § 425.502(d) outlines quality performance requirements for the four domains, stating that the ACO must report all measures in a domain and must score above the minimum attainment level determined by CMS on 70 percent of the measures in each domain. If the ACO fails to achieve the minimum attainment level on at least 70 percent of the measures in a domain, CMS will take compliance action. Additionally, the ACO must achieve the minimum attainment level for at least one measure in each of the four domains to be eligible to share in savings. In guidance, we have interpreted the quality performance requirements for domains to apply only to pay for performance measures because minimum attainment applies only to "certain" measures according to the definition of the quality performance standard in § 425.502(a)(3), and we have interpreted the reference to "certain" measures in § 425.502(a)(2) to mean pay for performance measures. As a result of this interpretation, we believe an inconsistency in the application of the policy goals outlined in our November 2011 final rule has arisen. In particular, we believe certain current policies are inconsistent with our goal of holding ACOs to higher quality reporting standards over time. Specifically, because measures are phased-in from pay for reporting to pay for performance over the course of an ACO's first 3-year agreement period, there are no pay for performance measures during PY1 and fewer pay for performance measures in each domain in PY2 compared to PY3. Thus, under our current interpretation of the rules, it is not possible to take compliance actions against an ACO in its first performance year for failure to achieve the minimum attainment level on at least 70 percent of the measures in a domain because there are no pay for performance measures on which to assess performance on a domain. Additionally, because there are fewer pay for performance measures in PY2 than in PY3, it is more likely that a compliance action would be taken against an ACO due to failure to meet the minimum attainment level on 70 percent of the pay for performance measures in a domain in PY2 than in PY3. Since publication of the November 2011 final rule, we have used the annual PFS rule to update the measures that ACOs are required to report. Each time a new measure is added, the measure is designated as pay for reporting for the first 2 years it is in use so that we can establish a performance benchmark prior to using it as a pay for performance measure. This, in turn, diminishes even further the number of pay for performance measures available in a domain in PY2 and PY3 or in an ACO's second or subsequent agreement period, making it more likely that ACOs would be subject to compliance action. Based on this experience, we believe it would be more consistent with our policy goals to take all measures into account when determining whether a compliance action should be taken against an ACO based on its quality performance in one or more domains.

Therefore, we propose to take all measures into account when determining ACO performance at the domain level for purposes of compliance actions. Additionally, we believe that compliance actions should be addressed at § 425.316 rather than in the quality reporting section, and therefore, we propose to move the provisions governing the specific performance levels at which a compliance action would be triggered from § 425.502 to § 425.316. Specifically, we propose the following modifications to our regulations:

- Revise introductory text at § 425.502(a) to make it clear that the quality performance standard is the overall standard the ACO must meet to qualify to share in savings.
- Replace the word "certain" in § 425.502(a)(2) and (3) with "all," so that the term "minimum attainment level" clearly applies to both pay for reporting and pay for performance measures.
- At § 425.502(a)(4), make modifications to remove the reference to the quality performance standard each time it appears to avoid causing confusion between the standards for individual measures and the overall quality performance standard.
- At § 425.502(b)(3), define "minimum attainment level" for both pay for reporting and pay for performance measures. We propose to set the minimum attainment level for pay for performance measures at the 30th percent or 30th percentile of the quality benchmark. We propose to set the minimum attainment level for pay for reporting measures at the level of complete and accurate reporting.
- At § 425.502(c)(2), we propose to revise the regulation text to specify that only pay for performance measures are assessed on a sliding scale.
- At § 425.502(c)(5), we propose to add a provision to specify that pay for reporting measures earn the maximum number of points for a measure when the minimum attainment level is met.
- Finally, we propose to modify § 425.502(d) to refer generally to compliance actions that may be taken for low quality performance. We propose to address specific levels of quality domain performance at which compliance action would be triggered by modifying § 425.316(c)(1).

d. Technical Change to Application of Flat Percentages for Quality Benchmarks

In the CY 2014 PFS final rule with comment period (78 FR 74761–74763), we finalized a methodology to spread clustered measures when setting quality benchmarks to promote a clinically meaningful assessment of ACO quality. Specifically, we finalized a policy that CMS would set quality benchmarks using flat percentages for a clustered measure when the national FFS data results in the 60th percentile for the measure are equal to or greater than 80.00 percent. We noted that the methodology would not apply to measures whose performance rates are calculated as ratios, for example, measures such as the two ACO Ambulatory Sensitive Conditions Admissions and the All Condition Readmission measures. Similarly, in the CY 2015 PFS final rule with comment period (79 FR 67925), we finalized a policy to address "topped out" measures by also setting benchmarks using flat percentages when the 90th percentile is equal to or greater than 95 percent. Although similar to the "cluster" policy finalized in the CY 2014 PFS final rule with comment period, we included measures whose performance rates are calculated as ratios. We believed this policy was appropriate because measures calculated and reported as ratios may become topped out and expressed our desire to treat all topped out measures consistently.

Since the CY 2015 PFS final rule with comment period, we have determined that converting measures calculated and reported as ratios into benchmarks expressed as percentiles and percentages creates confusion in the interpretation of quality results and may yield results that are contrary to the intended purpose of using flat percentages. As a result, we propose no longer applying the flat percentage policy to performance measures calculated as ratios, such as the Ambulatory Sensitive Conditions Admissions measures and the All-Cause Readmission measure. In addition, we propose two technical changes to address typographical errors in § 425.502(a)(1), which contains a duplicative reference to CMS, and in § 425.502(b)(2)(ii), which contains an extra "t" at the end of "percent."

e. Incorporation of Other Reporting Requirements Related to the PQRS

The Affordable Care Act gives the Secretary authority to incorporate reporting requirements and incentive payments from certain Medicare programs into the Shared Savings Program, and to use alternative criteria to determine if payments are warranted. Specifically, section 1899(b)(3)(D) of the Act affords the Secretary discretion to incorporate reporting requirements and incentive payments related to the physician quality reporting initiative (PQRI), under section 1848 of the Act, including such requirements and such payments related to electronic prescribing, electronic health records, and other similar initiatives under section 1848, and permits the Secretary to use alternative criteria than would otherwise apply (under section 1848 of the Act) for determining whether to make such payments. Under this authority, in the November 2011 final rule, we incorporated certain reporting requirements and payment rules related to the PQRS into the Shared Savings Program at § 425.504 for "eligible professionals" (EPs) who bill under the TIN of an ACO participant within an ACO. Thus, the Shared Savings Program rules provide that EPs who bill under the TIN of an ACO participant within an ACO may only participate under their ACO participant TIN as a group practice under PQRS under the Shared Savings Program for purposes of qualifying for a PQRS incentive (prior to 2015) or avoiding the payment adjustment (starting in 2015). In other words, the current regulations prohibit ACO participant TINs and the EPs billing through those TINs from participating in PQRS outside of the Shared Savings Program such that these entities may not independently report for purposes of PQRS apart from the ACO.

An ACO, reporting on behalf of its EPs for purposes of PQRS, is required to satisfactorily submit through the CMS web interface all of the ACO GPRO measures that are part of the Shared Savings Program quality performance standard. Under § 425.504(c), for 2016 and subsequent years, if an ACO fails to satisfactorily report all of the ACO GPRO measures through the CMS web interface each EP who bills under the TIN of an ACO participant within the ACO will receive a downward adjustment, as described in § 414.90(e) for that year. The current regulations do not provide any mechanism for these EPs to report separately or otherwise avoid the downward payment adjustment if the ACO fails to satisfactorily report on their behalf.

We stated in the November 2011 final rule that there were two main reasons for not allowing EPs who bill under the TIN of an ACO participant to report outside of their ACO for purposes of PQRS: (1) The Shared Savings Program is concerned with measuring the quality of care furnished by the ACO to its patient population as a whole, and not that of individual ACO providers/suppliers, and (2) allowing EPs that bill under the TIN of an ACO participant to earn more than one PQRS incentive goes against the rules of traditional PQRS (76 FR 67901 through 67902).

Since publication of the November 2011 final rule, we have gained experience with these policies and program operations and believe it is necessary to propose a change in policy in order to be able to accept and use data that is separately reported outside the ACO by EPs billing through the TIN of an ACO participant within an ACO for purposes of PQRS under limited circumstances for the final two years of PQRS before it sunsets and is replaced by the Quality Payment Program (QPP). We continue to believe that in most cases it is appropriate to assess EPs that bill through the TIN of an ACO participant under the PQRS as a group practice because as noted in the November 2011 final rule, the Shared Savings Program is concerned with measuring the quality of care furnished to an assigned population of FFS beneficiaries by the ACO, as a whole, and not that of individual ACO providers/suppliers. We believe this framework promotes clinical integration among the ACO providers/suppliers, which is an important aspect of the Shared Savings Program. In addition, it is consistent with the requirement under § 425.108(d) that each ACO provider/supplier must demonstrate a meaningful commitment to the mission of the ACO to ensure its likely success. Because an ACO cannot be successful in the Shared Savings Program without satisfying the quality reporting requirements, we believe a meaningful commitment by ACO providers/suppliers to the mission of the ACO includes assisting with and engaging in annual quality reporting through the ACO. Further, ACO reporting reduces burden for those in small or solo practices, and places a focus on population health by encouraging care coordination by ACO providers/suppliers to improve the health of the broader patient population for which they are responsible. Finally, we believe that such group reporting is consistent with group reporting under various other CMS initiatives and therefore, we do not intend to remove the requirement that ACOs report on behalf of the EPs who bill under the TIN of an ACO participant. As a corollary, we would continue to use ACO data preferentially for purposes of assessing or determining an EP's quality performance for purposes of programs such as PQRS or, by extension, the VM.

However, we believe that when an ACO does not satisfactorily report for purposes of PQRS, it may be appropriate to accept and use data that is reported outside the ACO. For PQRS to be able to accept and use data reported outside the ACO, however, we must modify the provision at § 425.504 prohibiting EPs that bill under the TIN of an ACO participant in an ACO to report separately for purposes of PQRS. We are therefore proposing to modify § 425.504 to lift the prohibition on separate reporting for purposes of the 2017 and 2018 PQRS payment adjustment. We believe this change to our program rules is necessary for several reasons.

First, we believe it is necessary to protect EPs that participate in ACOs that fail to satisfactorily report all of the ACO GPRO measures. Although 98 percent of ACOs successfully complete required quality reporting annually, there have been a few instances where an ACO has failed to report all of the required measures, for example, where an ACO has terminated its participation in the Shared Savings Program and did not quality report on behalf of the EPs that bill under the TIN of an ACO participant at the end of the performance year as required under our close-out procedures. In other instances, some ACOs continued to participate in the Shared Savings Program but failed to complete quality reporting in a timely manner. In these instances, the lack of complete quality reporting by the ACO translated into a failure for the EPs within the ACO to receive a PQRS incentive (or to avoid the PQRS downward adjustment) for that year.

Second, PQRS has transitioned away from providing incentive payments to applying only downward payment adjustments to payments under the Medicare Physician Fee Schedule, making it even more important for EPs to ensure they comply with the reporting requirements for PQRS. Under the current rules, EPs who bill under the TIN of an ACO participant within an ACO must ultimately rely on the ACO to report on their behalf. These EPs are only able to encourage and facilitate ACO reporting, but lack the ability to ensure that the ACO satisfactorily reports in order to prevent application of the payment adjustment. The proposed change to allow EPs to report separately would provide them a mechanism over which they have direct control to ensure satisfactory reporting occurs. Additionally, we note that because there are no more payment incentives under the PQRS, there is no longer any concern that an EP may inadvertently receive duplicative PQRS incentive payments from CMS. Specific issues and policies related to data reported by EPs apart from an ACO for purposes of avoiding the PQRS payment adjustment for payment years 2017 and 2018 are addressed in section III.H. of this proposed rule.

Third, under the VM, if the ACO satisfactorily reports quality data on their behalf, groups and solo practitioners that bill under the TIN of an ACO participant will be evaluated under the quality tiering methodology and could qualify for an upward payment adjustment if the ACO satisfactorily reports on their behalf. However, if the ACO does not satisfactorily report quality data as required under § 425.504 then groups and solo practitioners that bill under the TIN of an ACO participant fall into Category 2 for the VM and are subject to a downward payment adjustment. In section III.G. of this proposed rule, we make proposals for how quality data reported by EPs billing under the TINs of ACO participants that is reported apart from the ACO for purposes of avoiding the VM downward payment adjustment for 2017 and 2018.

For the reasons noted above, we believe it is appropriate to retain the provisions under § 425.504 that require the ACO to report all of the ACO GPRO measures to satisfactorily report on behalf of the EPs who bill under the TIN of an ACO participant for purposes of the PQRS payment adjustment, however, we are proposing to modify the provisions that prohibit EPs that bill under the TIN of an ACO participant to report apart from the ACO. Specifically, we propose to add a redesignated and revised paragraph at § 425.504(d) to address the requirement that the ACO report on behalf of the eligible professionals who bill under the TIN of an ACO participant for purposes of the of the 2017 and 2018 PQRS payment adjustment. Under this revised provision the prohibition on separate quality reporting for purposes of the PQRS payment for 2017 and 2018 would be removed. We also propose to make a technical change to § 425.504 to move existing § 425.504(d) to § 425.504(c)(5) because the intent of this provision was to parallel the language of § 425.504(b)(6) for purposes of the payment adjustment for 2016 and subsequent years. We reiterate our intent that data reported by an ACO would continue to be preferentially used for purposes of other CMS initiatives that rely on such data, including the PQRS and the VM, as discussed in sections III.I. and III.M., respectively. If an EP who bills under the TIN of an ACO participant chooses to report apart from the ACO, the EP's data may be used for purposes of PQRS and VM only when complete ACO reported data is not available.

Additionally, we note that under the Shared Savings Program, only the quality data reported by the ACO as required under § 425.500 would be used to assess the ACO's performance under the Shared Savings Program. In other words, quality data submitted separately from the ACO will not be considered under the Shared Savings Program. We request comments on this proposal.

f. Alignment With the Quality Payment Program (QPP)

1. Background and Introduction to the Quality Payment Program

The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10, enacted April 16, 2015), amended title XVIII of the Act to repeal the Medicare sustainable growth rate (SGR) and strengthen Medicare access by improving physician payments and making other improvements, to reauthorize the Children's Health Insurance Program, and for other purposes. The statute established the Merit-Based Incentive Payment System (MIPS), a new program for certain Medicare-participating practitioners. MIPS consolidates components of three existing programs, the PQRS, the Physician Value Modifier (VM), and the Medicare Electronic Health Record (EHR) Incentive Program for EPs. The statute also established incentives for participation in certain alternative payment models (APMs). On April 27, 2016, the Department of Health and Human Services (HHS) issued a proposed rule to implement key provisions of the MACRA and establish a new Quality Payment Program (QPP) (Medicare Program; Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models (81 FR 28162 through 28586) (the QPP proposed rule)). The QPP proposed rule proposes to implement a Quality Payment Program (QPP) that replaces a patchwork system of Medicare reporting programs with a flexible system that allows practitioners to choose from two paths that link quality to payments: the Merit-Based Incentive Payment System (MIPS) and Advanced Alternative Payment Models (APMs). As proposed, MIPS and the APM incentive will impact practitioner payments beginning in payment year 2019 based on 2017 reporting. MIPS is a new program that combines parts of the Physician Quality Reporting System (PQRS), Value Modifier (VM) and Medicare Electronic Health Record (EHR) Incentive Program into a single program in which eligible clinicians (ECs) will be measured over 4 categories which include quality, resource use, clinical practice improvement, and advancing care information. The QPP proposed rule specifically addresses ECs that participate in APMs and Advanced APMs, such as the Shared Savings Program. Specifically, for ECs participating in APMs, the QPP proposed rule proposes to:

- Establish criteria for reporting under each of the 4 categories. For example, the QPP proposed rule proposes for the quality performance category to use quality information submitted by the ACO through the CMS web interface to assess each EC billing under the TIN of an ACO participant. For assessing performance in the category of advancing care information for ECs billing under the TIN of an ACO participant, the QPP proposed rule proposes to aggregate EC-reported data to calculate an ACO score which is applied to each participating EC.

- Define an Advanced APM as one that meets several criteria including requiring participants to use certified EHR technology (CEHRT). As proposed under the QPP proposed rule, only Tracks 2 and 3 of the Shared Savings Program have the potential to meet all criteria necessary for designation as an Advanced APM. As proposed, in order to meet the CEHRT requirement, the Medicare Shared Savings Program must hold ACOs accountable for their participating eligible clinicians' use of CEHRT by applying a penalty or reward based on the degree of use of CEHRT (such as the percentage of EPs that are using CEHRT or the care coordination or other activities they perform using CEHRT).

We therefore reviewed the Shared Savings Program rules and identified several modifications to program rules that we believe must be proposed in order to support and align with this effort. These proposed modifications are discussed in more detail below and include:

- Revisions to §§ 425.504 and 425.506 to sunset Shared Savings Program alignment with PQRS and the EHR Incentive Program starting with quality reporting period 2017 (corresponding to payment year 2019).
- Addition of new paragraph § 425.506(e) and section § 425.508 to align with the proposed Quality Payment Program, including rules addressing annual assessment of an ACO ECs' use of CEHRT and for ACO reporting of certain quality measures to satisfy the quality performance category on behalf of the eligible clinicians who bill under the TIN of an ACO participant.
- Modifications to the EHR measure title and specifications necessary to align with the proposed QPP criteria for determining Advanced APM status, including scoring requirements for the limited circumstances when the measure is designated as pay for reporting.

2. Proposals Related to Sunsetting PQRS and EHR Incentive Program Alignment and Alignment With APM Reporting Requirements Under the Quality Payment Program

The Shared Savings Program has established rules at §§ 425.504 and 425.506 incorporating reporting requirements related to PQRS and the EHR Incentive Program. The current provision at § 425.504(c), addresses the PQRS payment adjustment for 2016 and subsequent years. Under the existing Shared Savings Program rules, which we propose to modify as discussed in the immediately preceding section, EPs who bill under the TIN of an ACO participant within an ACO may only participate under their ACO participant TIN as a group practice under the PQRS Group Practice Reporting Option for purposes of the PQRS payment adjustment under the Shared Savings Program. ACOs must submit all of the ACO GPRO measures to satisfactorily report on behalf of their eligible professionals for purposes of the PQRS payment adjustment. Under the current rules, if an ACO does not satisfactorily report, each EP participating in the ACO receives a payment adjustment under PQRS. As discussed in this rule, we have proposed to revise the rules to allow EPs who bill under the TIN of an ACO participant within an ACO to report separately from their ACO for purposes of the PQRS payment adjustment for 2017 and 2018.

At § 425.506, we address alignment with the EHR Incentive Program. Specifically, at § 425.506(a), we assert that ACOs, ACO participants, and ACO providers/suppliers are encouraged to develop a robust EHR infrastructure, which aligns with our eligibility criteria under § 425.112 that require ACOs to define care coordination processes, which may include the use of enabling technologies such as CEHRT. At § 425.506(b) and (c) we state that the quality measure regarding EHR adoption is measured based on a sliding scale and that it is weighted twice that of any other measure for scoring purposes and determining compliance with quality performance requirements for domains. To align with the EHR incentive program we state in § 425.506(d), that EPs participating in an ACO under the Shared Savings Program satisfy the CQM reporting component of meaningful use for the Medicare EHR Incentive Program when the EP extracts data necessary for the ACO to satisfy the quality reporting requirements under the Shared Savings Program from CEHRT and when the ACO reports the ACO GPRO measures through a CMS web interface. EPs are responsible for meeting the rest of the EHR incentive program requirements apart from the ACO.

As noted in this section of the proposed rule, the VM, PQRS and the EHR incentive programs are sunsetting and the last quality reporting period under these programs is proposed to be 2016, which would impact payments in 2018. Quality reporting under the QPP, as proposed, would begin in 2017 for payment year 2019. In order to align with the policies proposed in the QPP proposed rule, we propose to amend §§ 425.504 and 425.506 to indicate that these reporting requirements apply to ACOs and their EPs through the 2016 performance year. Specifically, at § 425.504(c) we propose to remove the phrase "for 2016 and subsequent performance years" each time it appears and add in its place the phrase "for 2016." As noted in section III.H. of this rule, we propose a technical change to redesignate paragraph (d) as paragraph (c)(5) and then to add new paragraph (d) to address PQRS alignment rules for the 2017 and 2018 PQRS payment adjustment. Similarly, at § 425.506, we propose to revise paragraph (d) to indicate that the last reporting year for the EHR Incentive program is 2016. As stated in this section of the proposed rule, the PQRS and EHR incentive programs are sunsetting and we have proposed that the Quality Payment Program will begin with the 2017 reporting year, and payment adjustments will take effect in 2019 for eligible clinicians.

In addition, we propose to require ACOs, on behalf of the ECs who bill under the TIN of an ACO participant, to report quality measures through the CMS web interface in order to satisfy the QPP quality performance category. Currently, ACOs are required under § 425.504 to report measures on behalf of the EPs who bill under the TIN of an ACO participant for purposes of PQRS. Under the QPP proposed rule, the quality data submitted to the CMS web interface by ACOs would satisfy the quality performance category for ECs participating in the ACO. Therefore, in order to align with the QPP proposals, we propose to add a new paragraph at § 425.508(a) that parallels the current requirement at § 425.504 for reporting on behalf of EPs who bill under the TIN of an ACO participant for purposes of PQRS. Specifically, we propose to require that ACOs, on behalf of ECs who bill under the TIN of an ACO participant, must submit all the ACO CMS web interface measures required by the Shared Savings Program using a CMS web interface, to meet reporting requirements for the quality performance category under MIPS. We also propose to maintain flexibility for EPs to report quality performance category data separately from the ACO, and therefore, do not propose to include a provision that would restrict an EP from reporting outside the ACO. The intent is to permit flexibility in reporting quality data. Under the Shared

Savings Program, however, no quality data reported apart from the ACO will be considered for purposes of assessing the quality performance of the ACO. We note that the QPP proposed rule does not address what, if any, separately reported EC quality performance category data might be considered, however, we believe it is important to retain flexibility in the event we finalize a policy under the QPP that would permit consideration of quality performance category data that is submitted separately by ECs participating in ACOs.

3. Proposals Related to Alignment With the Quality Payment Program (QPP)

In the QPP proposed rule (81 FR 28296) we outlined and defined the proposed criteria for Advanced APMs, APMs through which ECs would have the opportunity to become Qualified Participants as specified in section 1833(z)(3)(C) and (D) of the Act. First, under MACRA, for an APM to be considered an Advanced APM, it must meet three requirements: (1) Require participants to use certified EHR technology; (2) provide payment for covered professional services based on quality measures comparable to those used in the quality performance category of MIPS; and (3) be either a Medical home Model expanded under section 1115A(c) of the Act or bear more than an nominal amount of risk for monetary losses. In the QPP proposed rule, we proposed criteria for each of these requirements (81 FR 28296). As proposed under the QPP proposed rule, significant distinctions between the design of different tracks or options within an APM mean that certain tracks or options could meet the proposed Advanced APM criteria while other tracks or options may not. Because of this, only Tracks 2 and 3 of the Shared Savings Program would have the potential to meet all criteria necessary for designation as an Advanced APM. Under the approach discussed in the QPP proposed rule, while all ACOs would meet the criterion for provider payment based on quality measures comparable to those used in the quality performance category of MIPS, only Tracks 2 and 3 would appear to the meet the proposed financial risk standard to bear more than a nominal amount of risk for monetary losses.

For purposes of meeting the CEHRT requirement, we proposed in the QPP proposed rule to adopt for Advanced APMs the definition of CEHRT that is proposed for MIPS and the APM incentive under § 414.1305 (see 81 FR 28299 for more detailed information). We also noted in the QPP proposed rule that the statute does not specify the number of ECs who must use CEHRT or how CEHRT must be used in an Advanced APM. For this reason, we stated we believed it was reasonable to use discretion when proposing details on how APMs might meet criteria. In the QPP proposed rule, we proposed that an Advanced APM must require at least 50 percent of ECs who are enrolled in Medicare (or each hospital if hospitals are the APM participants) to use the certified health IT functions outlined in the proposed definition of CEHRT to document and communicate clinical care with patients and other health care professionals. However, we stated we believed it was appropriate to propose an alternative criterion for CEHRT use for the Shared Savings Program because, although the Shared Savings Program requires ACOs to encourage and promote the use of enabling technologies (such as EHRs) to coordinate care for assigned beneficiaries, the Shared Savings Program does not require a specific level of CEHRT use for participation in the program. Instead, the Shared Savings Program, as noted above, includes an assessment of EHR use as part of the quality performance standard which directly impacts the amount of shared savings/shared losses generated by the ACO. We therefore proposed an alternative criterion available only to the Shared Savings Program. Specifically, we proposed that the alternative criterion would allow the Shared Savings Program to satisfy the EHR criterion if it holds APM Entities accountable for their ECs' use of CEHRT by applying a financial penalty or reward based on the degree of CEHRT use (such as the percentage of ECs that use CEHRT or the engagement in care coordination or other activities using CEHRT). We noted that the current EHR quality measure at ACO #11, as noted above, assesses the degree to which certain ECs in the ACO successfully meet the requirements of the EHR Incentive Program, which requires the use of CEHRT by certain ECs in the ACO, and we stated that "[s]uccessful reporting of the measure for a performance year gives the ACO points toward its overall quality score, which in turn affects the amount of shared savings or shared losses an ACO could earn or be liable for, respectively." (81 FR 28300). Finally, we stated that we believed the alternative criterion meets the statutory requirement because the "proposed alternative criterion builds on established Shared Savings Program rules and incentives that directly tie the level of CEHRT use to the ACO's financial reward which in turn has the effect of directly incentivizing ever-increasing levels of CEHRT use among EPs."

In light of these QPP proposals, we are proposing several modifications to our program rules in order to align with the QPP proposals.

First, we propose to modify the title and specifications of the EHR quality measure (ACO #11). This measure is currently titled Percent of PCPs Who Successfully Meet Meaningful Use Requirements. Under the current Shared Savings Program rules, ACOs must report on and are held accountable for certain measures that make up the quality reporting standard. One of these measures, ACO #11, assesses the degree of CEHRT use by primary care physicians participating in the ACO and performance on this measure is weighted twice that of any other measure for scoring purposes. To calculate this measure, CMS collects information submitted by PCPs through the EHR Incentive Program and determines the rate of CEHRT use by PCPs participating in the ACO. Specifically, as explained in our guidance [*https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/2015-ACO11-Percent-PCP-Successfully-Meeting-Meaningful-Use-Requirement.pdf*], the denominator is based on all PCPs who are participating in the ACO in the reporting year under the Shared Savings Program and the numerator for the measure is based on the PCPs included in the denominator who successfully qualify to participate in either the Medicare or Medicaid EHR Incentive Program in the year indicated. Results of this measure are used in determining the ACO's overall quality score which in turn determines the ACO's final sharing/loss rate and the amount of shared savings earned (or shared losses owed) by the ACO.

Additionally, under the proposed policies included in the QPP proposed rule, ECs participating in an ACO would satisfy the Advancing Care Information category by reporting meaningful use of EHRs apart from the ACO (81 FR 28247, Table 15). Similar to the process currently used under the Shared Savings Program to determine what practitioners have met criteria for meaningful use for the ACO #11 measure, we anticipate accessing EC-reported data under the Advancing Clinical Information category to assess the ACO's overall use of CEHRT. Because the current measure only assesses the degree of use of CEHRT by primary care physicians participating in the ACO, we propose to modify the EHR measure to align with the QPP proposals. Specifically, we propose to change the specifications of the EHR measure to assess the ACO on the degree of CEHRT use by all providers and suppliers designated as ECs under the QPP proposed rule that are participating in the ACOs rather than narrowly focusing on the degree of use of CEHRT of only the primary care physicians participating in the ACO. We believe this modification to the specifications for ACO #11 would better align with the QPP proposals and ensure a subset of ACOs in the Shared Savings Program could qualify to be Advanced APM entities. We would also modify the title of the measure to remove the reference to PCPs. We believe the modification in the specifications of ACO #11 will be extensive and will require ECs to gain familiarity with the reporting requirements under the QPP proposed rule. We therefore propose that this measure would be considered a newly introduced measure and set at the level of complete and accurate reporting for the first two reporting period for which reporting of the measures is required according to our rules at § 425.502(a)(4). Therefore, the measure would be pay for reporting for the 2017 and 2018 performance years. We further propose to define requirements specific to this measure for the limited circumstances in which it is designated as pay for reporting. Specifically, we propose to include the requirement at § 425.506(e)(1) that during years in which ACO #11 is designated as a pay for reporting measure, in order for us to determine that the ACO has met requirements for complete and accurate reporting, at least one EC as we have proposed to define the term in the Proposed QPP rule, participating in the ACO must meet the reporting requirements under the Advancing Clinical Information category under the QPP, as proposed under the QPP proposed rule. We believe this proposal would safeguard the ability of Tracks 2 and 3 to fully meet all criteria for designation as Advanced APMs as proposed in the QPP proposed rule by ensuring the letter and spirit of the statutory criteria are met, even in the limited circumstances when ACO #11 is designated as pay for reporting under the Shared Savings Program. Beginning in the 2019 performance year, ACO #11 would be assessed according to the phase-in schedule noted in Table 36 which remains consistent with the current phase-in schedule under which the measure will be phased in to pay for performance starting with PY2 of an ACO's first agreement period and for all performance years of any subsequent agreement periods, assuming no major changes to the measure that would cause us to consider the measure to be a newly introduced measure and revert it to pay for reporting. We therefore further propose to add § 425.506(e)(2) reiterating our current requirement at § 425.506(b) that during pay for performance years, assessment of EHR adoption is measured based on a sliding scale. We do not intend that our proposal to use this measure to assess the degree of CEHRT use by ECs participating in the ACO for purposes of meeting the CERHT criterion for Advanced APMs under the QPP to change the way we treat the measure under pay for performance now. Similar to the current method used by the Shared Savings Program to calculate the EHR measure, the data will continue to be derived using EC reported EHR data that is required and collected by MIPS as proposed in the QPP proposed rule. Additionally, the measure will remain double weighted. We propose to retain the existing EHR measure requirements at § 425.506(a)–(c) and to modify § 425.506(d) to sunset the current EHR reporting requirement as noted in the prior section.

Finally, consistent with our statements in the QPP proposed rule as noted above, we do not believe that any additional modifications or exceptions to current program rules (other than the ones proposed here, specifically, that the measure specifications and title of ACO #11 be modified to include all ECs and not just PCPs, and the proposal for how an ACO would demonstrate complete and accurate reporting) must be made in order to be consistent with the spirit and intent of the statute and the QPP proposed criteria. Rather, the existing Shared Savings Program rules are sufficient to meet the QPP proposed criteria for Tracks 2 and 3 to be designated as eligible APMs because the EHR quality measure will always be used to impact the amount of shared savings or losses of an ACO, regardless of whether it is designated as pay for performance or pay for reporting. We note that the EHR measure has an especially significant impact on the overall quality scoring for an ACO because it is double-weighted compared to any other measure. In spite of this, we are considering additional options regarding the treatment of the EHR measure under the Shared Savings Program in order to further enhance the importance of this measure and its impact on an ACO's quality performance score and to improve alignment with the intent of the policies proposed in the QPP proposed rule. Specifically, we are considering whether to finalize a policy that would require the EHR measure to be P4P in all performance years, including the first year of an ACO's first agreement period. Additionally, we are considering whether to finalize a policy that would require the EHR measure to remain P4P, even when a new EHR measure is introduced or there are significant modifications to the specifications for the measure. Such modifications may require additional changes or alternative approaches to certain current Shared Savings Program rules related to quality benchmarking and scoring. We anticipate that if such modifications are made, they would only apply to the EHR measure and would not impact current scoring and benchmarking rules for other quality measures that make up the quality performance standard. For example, if a final policy is adopted that requires the EHR measure to remain P4P in the face of changes to the measure, we anticipate that we would need to establish a benchmark appropriate for the measure that does not depend on FFS or ACO generated data and distributing points on a sliding scale according to the benchmark because no FFS or ACO generated data would be available to do so in the first 2 years of the use of the new measure. For example, we may use a flat rate to assess performance or create a scale that aligns with our final QPP policies (for example, assessing ACO performance on a scale from 0–50 percent or 0–75 percent) and incrementally making points available depending on level of attainment. Additionally, we would consider exempting the EHR measure from "minimum attainment level" rules that would normally apply to a pay for performance measure, at least for the first 2 years of implementation and/or the first year of the first agreement period since the measure would be new to the ACO. Finally, we would consider whether these modifications should apply to the EHR measure only for tracks that could meet the requirements for designation as Advanced APMs under the forthcoming QPP final rule; we note that under the QPP proposed rule, only Tracks 2 and 3 would be designated as Advanced APMs. We seek comment on how best to conform to the intent and spirit of the QPP requirements to ensure that clinicians have assurance they are participating in an Advanced APM. We specifically seek comment on our proposals and the alternatives considered.

Finally, we note that the CMS web interface measures, including those proposed in the QPP proposed rule, are consistent across CMS reporting programs. We do not believe it is beneficial to propose CMS web interface measures for ACO quality reporting separately. Therefore, to avoid confusion and duplicative rulemaking, we propose that any future changes to the CMS web interface measures would be proposed through rulemaking for the QPP and would be applicable to ACO quality reporting under the Shared Savings Program.

4. Incorporating Beneficiary Preference Into ACO Assignment

a. Background

Under section 1899(c) of the Act, beneficiaries are required to be assigned to an ACO participating in the Shared Savings Program based on the beneficiary's utilization of primary care services rendered by physicians participating in the ACO. Medicare FFS beneficiaries do not enroll in the Shared Savings Program, and they retain the right to seek Medicare-covered services from any Medicare-enrolled provider or supplier of their choosing. No exclusions or restrictions based on health conditions or similar factors are applied in the assignment of Medicare FFS beneficiaries. Thus, a beneficiary's choice to receive primary care services furnished by physicians and certain non-physician practitioners that are ACO professionals in the ACO, determines the beneficiary's assignment to an ACO under the Shared Savings Program. As discussed in detail in the November 2011 Medicare Shared Savings Program final rule (76 FR 67851 through 67870), we finalized a claims-based hybrid approach (called preliminary prospective assignment with retrospective reconciliation) for assigning beneficiaries to an ACO. Under this approach, beneficiaries are preliminarily assigned to an ACO at the beginning of a performance year to help the ACO refine its care coordination activities, but final beneficiary assignment is determined at the end of each performance year based on where beneficiaries chose to receive a plurality of their primary care services during the performance year. We adopted this policy because we believe that the methodology balances beneficiary freedom to choose healthcare providers under FFS Medicare with the ACO's desire to have information about the FFS beneficiaries that are likely to be assigned at the end of the performance year. We believe this methodology accomplishes an appropriate balance because ACOs have the greatest opportunities to impact the quality and cost of the care of beneficiaries that choose to receive care from providers and suppliers participating in the ACO during the course of the year.

A beneficiary is eligible for assignment to an ACO under § 425.402 if the beneficiary had a primary care service with a physician who is an ACO professional, and thus, is eligible for assignment to the ACO under the statutory requirement to base assignment on "utilization of primary care services" furnished by physicians who are ACO professionals in the ACO. The beneficiary is then assigned to the ACO if the allowed charges for primary care services furnished to the beneficiary by all primary care physicians who are ACO professionals and non-physician ACO professionals in the ACO are greater than the allowed charges for such services provided by primary care physicians, nurse practitioners, physician assistants, and clinical nurse specialists who are ACO professionals in another ACO or not affiliated with any ACO and are identified by a Medicare-enrolled TIN. The second step of the assignment process considers the remainder of beneficiaries who have received at least one primary care service from an ACO physician with a specialty designation specified in § 425.402(c) , but have received no services from a primary care physician, nurse practitioner, physician assistant, or clinical nurse specialist either inside or outside the ACO. These beneficiaries are assigned to the ACO if the allowed charges for primary care services furnished by physicians who are ACO professionals in the ACO with one of the specialty designations specified in § 425.402(c) are greater than the allowed charges for primary care services furnished by physicians with such specialty designations in another ACO or who are not affiliated with any ACO and are identified by a Medicare-enrolled TIN. The "two step" assignment process simultaneously maintains the requirement to focus on primary care services in beneficiary assignment, while recognizing the necessary and appropriate role of specialists and non-physician practitioners in providing primary care services, such as in areas with primary care physician shortages. We revised this two-step claims based methodology in the June 2015 Final Rule as discussed in detail in that final rule (80 FR 32743 through 32758) and finalized a policy that would exclude services provided by certain physician specialties from step 2 of the assignment process.

Additionally, in the June 2015 final rule, and in response to stakeholders, we implemented an option for ACOs to participate in a new two-sided performance-based risk track, Track 3. Under Track 3, beneficiaries are prospectively assigned to the ACO at the beginning of the performance year using the same two-step methodology, based on the most recent 12 months for which data are available, which reflects where beneficiaries have chosen to receive primary care services during that period. The ACO is held accountable for beneficiaries that are prospectively assigned to it for the performance year. Under limited circumstances, a beneficiary may be excluded from the prospective assignment list, for example, if the beneficiary enrolls in Medicare Advantage or no longer lives in the United States or U.S. territories and possessions, based on the most recent available data in our beneficiary records at the end of the performance year. A beneficiary is not excluded from the ACO's prospective assignment list at the time of reconciliation because the beneficiary chose to receive most or all of his or her primary care during the performance year from providers and suppliers outside the ACO. Additionally, no beneficiaries are added to the ACO's prospective assignment list at the time of reconciliation because a beneficiary chose to receive a plurality of his or her primary care during the performance year from ACO professionals participating in the ACO. Offering this alternative approach to beneficiary assignment responds to stakeholders who expressed a desire for a prospective assignment approach. These stakeholders believe prospective assignment will provide more certainty about the beneficiaries for whom the ACO will be held accountable during the performance year, thus enabling ACOs to redesign their patient care processes to more efficiently and effectively improve care for specific FFS beneficiaries rather than for all FFS beneficiaries. We note, however, that such certainty is limited because prospectively aligned beneficiaries who meet the exclusion criteria specified in § 425.401(b) during the performance year will not be aligned to the ACO at the end of the year; and further, as noted, beneficiaries remain free under FFS Medicare to choose the healthcare providers from whom they receive services.

Because of uncertainty inherent in FFS Medicare where there is no beneficiary lock-in or enrollment, both patient advocacy groups and ACOs have expressed interest in and support for enhancing claims-based assignment of beneficiaries to ACOs by taking into account beneficiary attestation regarding the healthcare provider that they consider to be responsible for coordinating their overall care. Stakeholders believe that incorporating this information and giving beneficiaries the opportunity to voluntarily "align" with the ACO in which their primary healthcare provider participates will improve the patient centeredness of the assignment methodology. In theory, active beneficiary acknowledgement of the practitioner they believe to be responsible for their overall care could enhance engagement and the beneficiary's commitment to receive the bulk of his or her primary care from the designated practitioner. In turn, some stakeholders believe this could reduce year-to-year "churn" in beneficiary assignment lists and, in the case of prospective assignment, potentially increase certainty further because the increase in beneficiary engagement may encourage the beneficiary to receive care during the performance year from ACO providers/suppliers, to the extent that the beneficiary is aware of which providers and suppliers participate in the ACO. However, we note that such a process would not obligate the beneficiary to receive care from ACO providers/suppliers because the beneficiary would retain freedom under FFS Medicare to receive services from whichever provider or supplier the beneficiary chooses. Thus, while taking beneficiary attestation into account in the assignment algorithm may improve beneficiary engagement and therefore reduce year-to-year "churn" in beneficiary assignment of such patients, it may not result in the sort of certainty that some ACOs desire, particularly with respect to where beneficiaries choose to receive services.

To begin to address these concerns, the Center for Medicare & Medicaid Innovation (Innovation Center) began conducting a test of beneficiary attestation (which was referred to as voluntary alignment, a term that we will also use in the context of the Shared Savings Program) in the Pioneer ACO Model (see *https://innovation.cms.gov/initiatives/Pioneer-aco-model/*) for the 2015 performance year.

In the Pioneer ACO Model, for a Pioneer ACO to participate in voluntary alignment for performance year four (Pioneer ACO contract year 2015), the Pioneer ACO was required to submit an application to CMS in the summer of performance year three (Pioneer ACO contract year 2014) in which the ACO explained its plan for contacting beneficiaries. ACOs that were approved to participate in voluntary alignment were limited to contacting only those beneficiaries who appeared on the ACO's then current (Pioneer ACO contract year 2014) and prior year's (Pioneer ACO contract year 2013) prospective assignment lists.

The ACOs sent letters to beneficiaries during a specified period asking the beneficiaries to confirm whether a listed Pioneer Provider/Supplier was their "main doctor." The Innovation Center imposed certain safeguards on the participating ACOs to protect against actions that could improperly influence a beneficiary's decision to complete the voluntary alignment form. The ACOs collected responses and turned them in to CMS in fall 2014, before the start of the 2015 performance year. Beneficiaries who confirmed a care relationship with the Pioneer Provider/Supplier listed on the form, and met all other eligibility criteria for alignment, were prospectively aligned to the Pioneer ACO for the upcoming performance year, regardless of whether or not the practitioners participating in the Pioneer ACO rendered the plurality of the beneficiary's primary care services during the alignment period. We refer to the procedures used under the Pioneer ACO Model as "the manual process."

Because the testing of beneficiary attestation in the Pioneer ACO Model was just beginning at the time of the publication of the December 2014 proposed rule, in that proposed rule we indicated our interest in beneficiary attestation, but did not make any specific proposals. However, we welcomed comments on whether it would be appropriate to offer a beneficiary attestation process to ACOs participating under two-sided risk financial arrangements under the Shared Savings Program in the future (79 FR 72826 through 72829). We noted that if we were to offer a beneficiary attestation process for ACOs in performance-based risk tracks, we would anticipate initially implementing beneficiary attestation in a manner consistent with the beneficiary attestation process tested under the Pioneer ACO Model (79 FR 72829).

Beneficiary and ACO participation in and experience with voluntary alignment under the Pioneer ACO Model to date has been mixed. Initially, beneficiaries often seemed confused about the implications of attesting to a care relationship with a Pioneer Provider/Supplier, based on the letters they received from Pioneer ACOs. Beneficiaries, for example, were often unfamiliar with the name of the Pioneer ACO. Although most Pioneer ACOs initially expressed high interest in beneficiary attestation, only half participated. Those that did not participate cited cost/benefit concerns. To address concerns expressed by ACOs and beneficiaries, the beneficiary attestation process was updated for the Pioneer ACO Model for PY 2016, with letters sent to beneficiaries during the summer of 2015. The new beneficiary attestation process includes updated language in the letters to beneficiaries and the attestation form to reduce beneficiary confusion. The letters now include plainer language, refer to a specific healthcare provider (in addition to the ACO), and Pioneer Providers/Suppliers are permitted to discuss beneficiary attestation with beneficiaries and respond to questions. Other significant changes to the process include a longer voluntary alignment period and the ability for ACOs to provide the letter/form to beneficiaries via email, patient portal, or other electronic method (in which case the forms must be returned with a "wet-ink" signature, such as by returning the original signed form by mail. (We continue to view this updated process to be a manual process.) In addition there was a change to the voluntary alignment eligibility criteria. For performance year four (Pioneer ACO contract year 2015), only those beneficiaries who were identified on a Pioneer ACO's prospective alignment list from performance year two (Pioneer ACO contract year 2013) or performance year three (Pioneer ACO contract year 2014) were eligible to voluntarily align with the Pioneer ACO for performance year four, assuming all other eligibility criteria were met. For performance year five (Pioneer ACO contract year 2016), CMS changed the criteria to allow beneficiaries to voluntarily align into the performance year five aligned population if, among other requirements, the beneficiary had at least one paid claim for a Qualified E/M service, as defined in section 2.4 of Appendix C of the Pioneer ACO Agreement, furnished by a Pioneer Provider/Supplier on or after January 1, 2013. Based on some initial feedback, beneficiaries appear to be wary of the implications of designating a "main doctor" but are much more amenable to this type of information request when it comes from their physician or other practitioner, rather than from an ACO. However, information is not yet available on the impact or results of the modifications made to the beneficiary attestation process in the Pioneer ACO Model. The Next Generation ACO Model, which started operation on

January 1, 2016, includes a beneficiary attestation policy similar to the updated manual process used under the Pioneer ACO model. In order for a Medicare FFS beneficiary to be eligible to voluntarily align with a Next Generation ACO for performance year two (Next Generation ACO contract year 2017), the beneficiary must have had at least one paid claim for a qualified evaluation and management service on or after January 1, 2014, with an entity that was a Next Generation Participant during performance year one, among other requirements.

To date, the Innovation Center has done limited analyses of the updated voluntary alignment process for effects on beneficiary engagement. Early experience indicates that for the participating ACOs, the number of prospectively assigned beneficiaries per ACO increased by 0.2 to 2.7 percent relative to the number of beneficiaries who would have otherwise been assigned. However, there is not yet enough information to determine whether beneficiary attestation under the manual process has had an impact on increasing certainty that a beneficiary will continue to choose to receive primary care or other services from practitioners participating in an ACO. For example, we would like to know how many of the beneficiaries who "attested" into alignment to the ACO continued to seek primary care services from ACO professionals during the performance year, which might demonstrate increased engagement on the part of the beneficiary. The Innovation Center found that ACOs were implementing the beneficiary attestation process under the Pioneer ACO Model as they described in their applications, and no marketing abuses have been observed to date.

Based on valuable experience gained through development and testing of beneficiary attestation processes through the Pioneer ACO Model, the manual process developed thus far appears to be resource intensive and may not significantly impact beneficiary assignment to ACOs. We also note that a similar manual process for sending letters to beneficiaries to provide them notice of their opportunity to opt out of claims data sharing was removed from the Shared Savings Program in the June 2015 final rule (see 80 FR 32743). This data sharing opt out process was removed because it was resource intensive and cumbersome for ACOs and CMS, and was confusing for beneficiaries. Instead, based on stakeholder comments, we finalized a process to provide beneficiaries the opportunity to decline claims data sharing directly by contacting the Medicare program (through 1–800–MEDICARE) rather than through the ACO. This more direct process started at the end of 2015 and so far appears to be working well, as it has not generated the number of complaints and concerns raised by the initial manual process.

b. Proposals

We continue to believe that it may be desirable to incorporate beneficiary attestation into the assignment of beneficiaries to ACOs participating in the Shared Savings Program, to supplement and enhance the current claims-based algorithm driven methodology as described in more detail in this section of the proposed rule. We agree with stakeholders that supplementing the current assignment process with a voluntary alignment process that incorporates beneficiary attestation about their "main doctor" could help ACOs to increase patient engagement, improve care management and health outcomes, and lower expenditures for beneficiaries. Incorporating beneficiary attestation into the beneficiary assignment process could further strengthen the current claims-based, two-step assignment process. For example, although we defined certain HCPCS codes at § 425.20 as being "primary care services," the use of these codes may not fully capture the extent of the primary care relationship a beneficiary has with his or her provider. Supplementing the claims-based assignment algorithm with beneficiary attestations could further assure that beneficiaries are assigned to ACOs based on their relationship with providers that they believe to be truly responsible for their overall care.

We believe that it would be appropriate to implement, at a minimum, a voluntary alignment process under the Shared Savings Program that would be similar to the updated manual process we have implemented under the Pioneer ACO Model and that will be used under the Next Generation ACO Model. However, based on the valuable knowledge and experience we have gained through these Innovation Center models, we are concerned that the manual voluntary alignment process used for the Pioneer ACO Model and that will be used under the Next Generation ACO Model is resource intensive for both ACOs and CMS. The voluntary alignment process under the Pioneer ACO Model requires individual ACOs to directly obtain information from beneficiaries by sending them a form letter approved by CMS that includes a copy of a CMS-approved form that the beneficiary may complete to confirm their care relationship with a provider or supplier that is participating in the ACO (that is, their "main doctor"), whose services are considered in the alignment process. The ACOs then communicate these beneficiary attestations to CMS. However, not all beneficiaries that submit an attestation form may be eligible to be aligned to the ACO. Accordingly, we must review the submissions, and provided the beneficiary is otherwise eligible for alignment to the ACO, this confirmation (or attestation) is then used to align the beneficiary to the ACO. If we were to implement a similar manual process under the Shared Savings Program, we believe it would be appropriate to limit voluntary alignment to Track 3 ACOs for the reasons explained later in this section. Additionally, the timing and requirements of the process would prohibit beneficiaries from voluntarily aligning to ACOs that initially join the Shared Savings Program under Track 3 for the ACO's first performance year because, consistent with the coluntary alignment process under the Pioneer ACO and Next Generation ACO models explained above, an ACO would only be permitted to contact beneficiaries that were aligned prospectively to the ACO in the current or prior years. Thus, a beneficiary's designation of an ACO professional as responsible for coordinating their overall care would impact an ACO's prospective assignment list starting in PY2, assuming the ACO met all requirements necessary for the incorporation of this information during PY1, including applying for participation in voluntary alignment, sending letters, collecting beneficiary preferences, and timely submitting all required information to CMS.

Because of the limitations of the manual process, we have considered ways that voluntary alignment might be implemented in a more automated and direct way under the Shared Savings Program, potentially having a more significant impact on beneficiary engagement while reducing burdens on ACOs, ACO participants, ACO providers/suppliers, ACO professionals, beneficiaries, and CMS. Automating a process for Medicare FFS beneficiaries to designate their "main doctor" or the other healthcare provider they believe is responsible for their overall care could align with agency goals to provide increased focus on patient centered care, and improve beneficiary engagement. We believe strengthening primary care is critical to an effective health care system. Automating a process for beneficiaries to designate their "main doctor" or the healthcare provider they believe is responsible for their overall care could encourage beneficiaries to partner with a healthcare provider to better coordinate their care, including care with specialists, and would help to support the continued development of a health care system that results in healthier people and smarter spending of our health care dollars. Incorporating beneficiary preferences through voluntary alignment could also help to increase the accuracy of the assignment process. If a beneficiary is aligned to the ACO in which the healthcare provider who they believe is responsible for coordinating their overall care is participating, there may be an increased probability that the beneficiary's care will be coordinated, resulting in smarter spending of health care dollars, including spending on care by specialists.

We are therefore proposing to implement an automated approach under which we could determine which healthcare provider a FFS beneficiary believes is responsible for coordinating their overall care (their "main doctor") using information that is collected in an automated and standardized way directly from beneficiaries (through a system established by us, such as *MyMedicare.Gov*), rather than requiring individual ACOs, ACO participants, or ACO professionals to directly obtain this information from beneficiaries annually and then communicate these beneficiary attestations to CMS. We believe such an approach would be more efficient for ACOs and their participants, beneficiaries, and CMS. We anticipate that, to the extent feasible, the operational process for beneficiaries to voluntarily align with an ACO by designating a "main doctor" or primary healthcare provider would be incorporated into existing processes. For example, currently Medicare FFS beneficiaries already have the ability to obtain an account at *www.MyMedicare.gov* and save information about their "favorite" providers from that Web site's Physician Compare function, so one possibility would be to include an additional feature in *MyMedicare.Gov* that would allow beneficiaries to indicate which of their "favorite" healthcare providers they consider to be responsible for their overall care. Another possibility would be to permit beneficiaries to directly choose their "main doctor" through 1–800–Medicare or through Physician Compare with a link to *MyMedicare.Gov*, similar to the mechanism that is currently available to select a "favorite" healthcare provider through Physician Compare. We would notify beneficiaries of this opportunity and encourage them to designate their primary healthcare provider and explain how to do this through beneficiary outreach materials such as through the Medicare & You Handbook (see *https://www.medicare.gov/medicare-and-you/medicare-and-you.html*), the required Shared Savings Program notifications under § 425.312, and/or other beneficiary outreach activities or materials. CMS would issue, either directly or indirectly through template language, all written communications to beneficiaries detailing the automated process for voluntary alignment.

We propose to make such an automated mechanism available for beneficiaries to voluntarily align with the provider or supplier that they believe is responsible for coordinating their overall care starting early in 2017, making it possible for us to use beneficiary attestations for assigning beneficiaries to ACOs in all three tracks for the 2018 performance year. For example, if the automated mechanism is available for beneficiaries in early 2017, we would be able to use the information in the fall of 2017 to develop ACO assignment lists for 2018 for ACOs that are currently participating in the Shared Saving Program, as well as those applying for participation. Voluntary alignment data would be accessed and incorporated in the beneficiary assignment process each time we run the assignment algorithm. Under the automated approach, beneficiaries would be able to change their attestation about their "main doctor" at any time, however, we note there may be a lag in using the information to update an ACO's assignment list depending on the timing of the beneficiary's updated designation and the track under which the ACO is participating. For example, we propose that beneficiaries who designate an ACO professional in a Track 3 ACO as their "main doctor" would be prospectively assigned to that Track 3 ACO based on their designation prior to the start of the performance year as currently provided under § 425.400(a)(3). These beneficiaries would remain assigned to the Track 3 ACO until the end of the benchmark or performance year, even if they subsequently designate a practitioner outside the ACO as their "main doctor", unless they meet any of the exclusion criteria under § 425.401(b). We considered incorporating voluntary alignment as part of the exclusion criteria under 425.401(b), however, we believe it would be appropriate, when incorporating voluntary alignment for Track 3 ACOs, to continue the current prospective assignment policy provided under § 425.400(a)(3) because the intent of prospective assignment is to provide stability in ACOs' beneficiary assignment lists to allow ACOs to coordinate care appropriately for the patients assigned to them. This policy would also align with our policy regarding the SNF 3-day rule waiver under § 425.612, which is limited to eligible beneficiaries who have been prospectively aligned to a Track 3 ACO, because it is important for the ACO to have clear information about which beneficiaries are eligible to receive SNF services pursuant to the waiver. The updated designation would, however, be considered when conducting beneficiary assignment for the subsequent benchmark or performance year.

Further, we propose to incorporate voluntary alignment for ACOs in Tracks 1 and 2 on a quarterly basis; that is, beneficiaries who are not currently assigned to a Track 3 ACO and who voluntarily align with a healthcare provider that is an ACO professional participating in an ACO under Track 1 or 2 would be reflected in the ACO's next preliminary prospective or final assignment list as provided under § 425.400(a)(2). We believe this policy would be appropriate because it aligns with the current timing for updates to Track 1 and 2 ACO assignment lists.

Finally, we propose that if a beneficiary voluntarily aligns with a provider or supplier whose services would be considered in assignment but who is not participating in an ACO as an ACO professional, the beneficiary would not be eligible for alignment to an ACO, even if the beneficiary would have otherwise been assigned to an ACO under our claims-based approach.

We further propose that, if this automated voluntary alignment process is not operationally ready for implementation under the proposed timeframe, we would implement a manual voluntary alignment process for Track 3 ACOs only that builds upon experience previously gained under the Pioneer ACO Model. Because a manual voluntary alignment process is resource intensive for both ACOs and CMS, we believe that if it were necessary to adopt a manual voluntary alignment process under the Shared Savings Program, it would be appropriate to initially limit it to ACOs participating in the Shared Savings Program under Track 3 because beneficiaries are prospectively aligned to Track 3 ACOs (as they are to ACOs under the Pioneer ACO Model and the

Next Generation Model). The process and timing for sending letters to beneficiaries regarding voluntary alignment under the manual process was developed specifically for prospective alignment and for a limited number ACOs. It is likely that attempting to implement such a manual process for the hundreds of ACOs in Track 1 and Track 2, whose beneficiaries are only preliminarily prospectively aligned with retrospective reconciliation, would result in operational challenges for ACOs and CMS and could have unintended consequences that could be confusing or harmful to beneficiaries. Because it is impossible to anticipate what issues might arise if we were to try to implement a manual process across a large number of ACOs operating under a preliminary prospective assignment methodology with retrospective reconciliation, we are not confident at this time that we can propose appropriate procedures and any additional safeguards that might be necessary to allow implementation in all tracks. Therefore, we propose that if an automated process is not available to allow beneficiaries to designate their primary healthcare provider in time to allow the information to be considered for beneficiary assignment for performance year 2018, we would implement voluntary alignment in a step-wise fashion over time, beginning with ACOs in Track 3, whose beneficiaries are prospectively assigned. Limiting voluntary alignment to ACOs to which beneficiaries are prospectively aligned would permit ACOs and CMS to initially focus limited resources on voluntary alignment efforts on a population of beneficiaries that can be identified for targeting and outreach regarding the voluntary alignment process and the benefits of designating an ACO professional as responsible for coordinating their overall care.

More specifically, we propose that if we determine, by no later than spring 2017, that an automated voluntary alignment process is not ready for implementation to allow beneficiaries to voluntarily align with ACO across all three Tracks for the 2018 performance year, then we would implement an alternative manual voluntary alignment process to allow beneficiaries to align with Track 3 ACOs for the 2018 performance year and until such time as an automated process is available. This proposed alternative manual voluntary alignment process for Track 3 ACOs would be similar to the updated process that was used under the Pioneer ACO Model to allow beneficiaries to voluntarily align with participating ACOs for the 2016 performance year and that we will follow under the Next Generation ACO Model for the 2017 performance year. Early each year, starting in 2017, Track 3 ACOs would notify us as to whether they want to participate in voluntary alignment for the upcoming performance year. Specifically, similar to the process used under the Pioneer ACO Model and the Next Generation ACO Model, each spring starting in 2017, those Track 3 ACOs that have notified CMS that they would like to participate in voluntary alignment would be required to provide us with a list of the beneficiaries they plan to contact to request that the beneficiary designate an ACO professional whose services are considered in assignment as their "main doctor." The ACOs must also submit to CMS for approval the criteria used to identify the listed beneficiaries. We would review these beneficiary lists to determine if the beneficiary is eligible to be contacted regarding voluntary alignment depending on whether the beneficiary was prospectively assigned yo the ACO in prior performance years, similar to the approach used under the Pioneer ACO Model and the Next Generation ACO Model approach as described above. ACOs could then contact the eligible beneficiaries by sending them a form letter approved by CMS, similar to the letter ACOs sent under the Pioneer ACO Model for 2016, that would include a copy of a CMS-approved form that the beneficiary could complete to confirm their care relationship with an ACO professional, whose services are considered in the assignment process, who the ACO believes may be their "main doctor." Alternatively, the ACO could provide an opportunity for beneficiaries to obtain a copy of the CMS-approved form in the offices of ACO professionals that furnish primary care services on which assignment is based.

Under the manual voluntary alignment process, by September of each year, Track 3 ACOs participating in voluntary alignment for the upcoming performance year would notify CMS as to which beneficiaries had agreed to voluntarily align with their ACO for the upcoming performance year by submitting a form designating an ACO professional whose services are considered in alignment as responsible for coordinating their overall care. We would verify that the beneficiaries are still eligible for assignment to the ACO, and prospectively assign all eligible beneficiaries to the Track 3 ACO for the upcoming performance year. We would repeat this process annually; that is, under this process, beneficiaries would be required to voluntarily align each year by submitting a new form confirming a care relationship with an ACO professional whose services are used in assignment. This approach would enable us to begin the process of incorporating beneficiary attestations into the assignment of beneficiaries to Track 3 ACOs until a more automated, direct method of voluntary alignment is operationally feasible. We believe even this more limited approach to voluntary alignment may increase patient centeredness over the current approach of assigning beneficiaries to ACOs based only on the claims-based algorithm driven methodology for the reasons discussed above and because some level of additional beneficiary engagement in the alignment process may be preferable to no beneficiary engagement.

Therefore, regardless of process (manual or automatic), we are proposing to begin to incorporate beneficiary attestation into the assignment methodology for the Shared Savings Program, effective for assignment for the 2018 performance year. In brief, under the proposal, an eligible beneficiary would be assigned to an ACO based on the existing claims-based assignment process unless the beneficiary has designated a healthcare provider as being responsible for their overall care. If an eligible beneficiary has made such a designation then the voluntary alignment would override the claims based assignment process. Under an automated process, beneficiaries would be able to modify their designation at any time (not just annually, as under a manual process), however, as noted above, there may necessarily be a lag before that information can be incorporated into the assignment methodology for purposes of determining an ACO's assignment list, depending on the timing of the designation and the track in which the ACO is participating. The latest that the information would be updated would be prior to the start of the next performance year at a timepoint designated by CMS in cases where beneficiaries are prospectively aligned to a Track 3 ACO. There may also be a lag when a beneficiary voluntarily aligns with a practitioner identified by an NPI who is an ACO professional in an ACO, but chooses to leave the ACO during a performance year. For example, there may be situations in which an eligible beneficiary voluntarily aligns to a practitioner billing under ACO participant TIN A in ACO A participating in Track 3 and becomes prospectively assigned for performance year 2018 on that basis. In the first quarter of 2018, the practitioner reassigns billing rights to ACO participant TIN B in ACO B, thus switching ACOs. Under our proposal, the beneficiary would remain prospectively aligned to ACO A for the duration of performance year 2018. Similarly, there may be situations in which an eligible beneficiary voluntarily aligns to a practitioner billing under ACO participant TIN in ACO C participating in Track 1 using an automated process and becomes preliminarily prospectively aligned during the first quarter of a performance year. In the second quarter of the performance year, the practitioner reassigns billing rights to a non-ACO participant TIN. Under our proposals, the next time a preliminary prospective assignment list is issued, the beneficiary would no longer appear on ACO C's list. Moreover, voluntary alignment in no way limits or changes benefits under FFS Medicare. Because of this, a beneficiary that meets the eligibility criteria may voluntarily align with a practitioner participating in an ACO, become aligned to the ACO, but subsequently choose to receive all his or her primary care from a practitioner that is unaffiliated with the ACO. In this case, the beneficiary would continue to be assigned to the ACO based upon the beneficiary's designation of an ACO professional as their "main doctor" for the remainder of the performance year under the manual process, and indefinitely until the beneficiary changes his or her designation under the automated process. Finally, we can imagine a scenario where a beneficiary designates as their "main doctor" a practitioner that is unaffiliated with any ACO and therefore the beneficiary is not assigned to an ACO even though the ACO's practitioners provided a plurality of the beneficiary's primary care services and would have otherwise been held accountable for the beneficiary's care. Given the high interest in taking beneficiary preferences for alignment into account and the potential for improving beneficiary engagement, we believe these scenarios, which may involve undesirable effects on the accuracy of beneficiary alignment, can be limited when beneficiaries are provided sufficient information about the importance of keeping the designation of their "main doctor" up to date.

We emphasize that we do not intend for the voluntary alignment process (whether automated or manual) to be used as a mechanism for ACOs (or their ACO participants, ACO providers/suppliers, ACO professionals or other individuals or entities performing functions or services on behalf of the ACO) to target beneficiaries for whose treatment the ACO might expect to earn shared savings, or to avoid those for whose treatment the ACO might be less likely to generate shared savings. Further, as discussed in more detail later in this section, we do not believe ACOs or others should be permitted to offer gifts or other inducements to beneficiaries, nor should they be allowed to withhold or threaten to withhold services, for the purposes of coercing or influencing beneficiaries' voluntary alignment decisions. However, we believe it is important to promote engagement and discussion between beneficiaries and their healthcare providers and therefore do not propose to prohibit an ACO or its ACO participants, ACO providers/suppliers, or ACO professionals from providing a beneficiary with accurate descriptive information about the potential patient care benefits of designating an ACO professional as responsible for the beneficiary's overall care.

Accordingly, we propose to revise the regulations governing the assignment methodology to add a new paragraph (e) to § 425.402. Under this paragraph, if an automated system is available by spring of 2017 to allow a beneficiary to designate an ACO professional whose services are used in alignment as responsible for coordinating their overall care and for CMS to process the designation electronically, then the voluntary alignment process would be available for ACOs participating in Track 1, Track 2, or Track 3, as specified in § 425.600(a) of this part. However, if such an electronic system is not available by spring of 2017, then CMS will specify the form and manner in which a beneficiary may designate an ACO professional whose services are used in assignment as responsible for coordinating their overall care using a manual process, but the voluntary alignment process will be limited to ACOs participating in Track 3 until an automated system is available. In either case, under the proposal, beginning in performance year 2018 beneficiaries that have voluntarily aligned with an ACO by designating an ACO professional whose services are used in assignment as responsible for coordinating their overall care will be added to the ACO's list of assigned beneficiaries, for a performance year under the following conditions:

- The beneficiary must have had at least one primary care service with a physician who is an ACO professional in the ACO and who is a primary care physician as defined under § 425.20 of this subpart or who has one of the primary specialty designations included in § 425.402(c).
- The beneficiary must meet the assignment eligibility criteria established in § 425.401, and must not be excluded by the criteria at § 425.401(b).
- The beneficiary must have designated an ACO professional who is a primary care physician as defined at § 425.20 of this part, a physician with a specialty designation included at § 425.402(c) of this subpart, or a nurse practitioner, physician assistant, or clinical nurse specialist as responsible for their overall care.
- The designation must be made in the form and manner and by a deadline determined by CMS. In contrast, if a beneficiary designates a provider or supplier outside the ACO, who is a primary care physician as defined at § 425.20 of this part, a physician with a specialty designation included at § 425.402(c), or a nurse practitioner, physician assistant, or clinical nurse specialist, as responsible for coordinating their overall care, the beneficiary will not be added to the ACO's list of assigned beneficiaries for a performance year, even if the beneficiary would otherwise be included in the ACO's assigned beneficiary population under the assignment methodology in § 425.402(b).

Further, we propose that the ACO, ACO participants, ACO providers/suppliers, ACO professionals, and other individuals or entities performing functions or services related to ACO activities are prohibited from directly or indirectly, committing any act or omission, or adopting any policy that coerces or otherwise influences a Medicare beneficiary's decision to designate or not designate an ACO professional as responsible for coordinating their overall care, including but not limited to the following:

- Offering anything of value to the Medicare beneficiary as an inducement for influencing the Medicare beneficiary's decision to designate or not to designate an ACO professional as responsible for coordinating their overall care. Any items or services provided in violation of this prohibition will not be considered to have a reasonable connection to the medical care of the beneficiary, as required under § 425.304(a)(2);

- Withholding or threatening to withhold medical services or limiting or threatening to limit access to care; and
- Including any voluntary alignment or change of preference forms requiring a beneficiary signature with any other materials or forms, including but not limited to any other materials requiring the signature of the Medicare beneficiary. (We note this requirement would only be applicable if we implement a manual process);

To maintain flexibility for ACOs, ACO participants, ACO providers/suppliers, ACO professionals, beneficiaries, and CMS, we would intend to provide further operational details regarding the voluntary alignment process and the applicable implementation timelines through subregulatory guidance and other outreach activities.

We seek comments on this proposal, on the effective date, and on any other related issues that we should consider for the final rule to address issues related to voluntary alignment under the Shared Savings Program. In particular, we seek comment on whether voluntary alignment is an appropriate mechanism for assigning beneficiaries retrospectively to an ACO. Specifically, is it appropriate to retrospectively align a beneficiary to an ACO, if the beneficiary designated an ACO professional whose services are used in assignment as responsible for the beneficiary's overall care, but did not receive a plurality of primary care services from ACO professionals in the ACO during the performance year? We seek comment on whether including voluntary alignment information in our assignment algorithm should be discretionary, that is, whether ACOs should be permitted to opt into or out of voluntary alignment. We seek comment on whether we should exclude a beneficiary from an ACO's prospective assignment list for a performance year if later during the performance year the beneficiary voluntarily aligns with a healthcare provider that is not an ACO professional in the ACO. We also seek input on how concerns about ACO avoidance of at risk beneficiaries might be addressed.

We also note that under the proposed automated voluntary alignment process, a beneficiary's designation of a healthcare provider as responsible for coordinating their overall care would stay in effect until the beneficiary chose to make a subsequent change. We have concerns that in some cases a beneficiary may develop a closer healthcare relationship with a primary care provider who is different than the one they initially designated but the beneficiary might not necessarily change their designation to reflect this new choice. However, requiring a beneficiary to update his or her designation annually seems burdensome. Therefore, under the proposal we would continue to use their designation and rely on appropriate information shared with beneficiaries at the point of care to ensure the beneficiary's designation is kept up to date. We seek comment on this issue and our proposal under the automated system to continue to use a beneficiary's designation of the healthcare provider responsible for coordinating their overall care until it is changed.

In addition, although we are not proposing to specify operational processes in regulations, nevertheless we also welcome suggestions regarding the operational process, implementation timelines, and related issues regarding the process for beneficiaries to voluntarily align with an ACO, including how to strengthen ACOs' beneficiary engagement activities. We note that although we are proposing to establish a process under which beneficiaries may designate their "main doctor" who they consider responsible for coordinating their overall care, in establishing the operational processes for allowing beneficiaries to designate their "main doctor" we may not explicitly use the phrase "responsible for coordinating overall care" which we have included in the proposed provision at § 425.402(e). Instead, we may consider using other terminology based on focus group testing and/or other feedback from beneficiary representatives. We welcome comments on what terminology would be preferable to ensure beneficiaries understand the significance of designating a provider or supplier as responsible for coordinating their overall care. We will consider such suggestions further as we develop program guidance and outreach activities for beneficiaries and ACOs.

3. SNF 3-Day Rule Waiver Beneficiary Protections

a. Background

The Medicare SNF benefit is for beneficiaries who require a short-term intensive stay in a SNF, requiring skilled nursing, or skilled rehabilitation care, or both. Under section 1861(i) of the Act, beneficiaries must have a prior inpatient hospital stay of no fewer than three consecutive days in order to be eligible for Medicare coverage of inpatient SNF care. In the June 2015 final rule (80 FR 32804 through 32806), we provided ACOs participating in Track 3 with additional flexibility to attempt to increase quality and decrease costs by allowing these ACOs to apply for a waiver of the SNF 3-day rule for their prospectively assigned beneficiaries when they are admitted to certain "SNF affiliates," that is, SNFs with whom the ACO has executed SNF affiliate agreements. (See § 425.612(a)(1)). Waivers are effective upon CMS notification of approval for the waiver or the start date of the ACO's participation agreement, whichever is later. (See § 425.612(c)). We stated in the June 2015 final rule that the SNF 3-day rule waiver would be effective for services furnished on or after January 1, 2017. Program requirements for this waiver are codified at § 425.612. These requirements are primarily based on criteria previously developed under the Pioneer ACO Model. Specifically, under § 425.612(a)(1), we waive the requirement in section 1861(i) of the Act for a 3-day inpatient hospital stay prior to a Medicare covered post-hospital extended care service for eligible beneficiaries prospectively assigned to ACOs participating in Track 3 that have been approved to implement the waiver that receive otherwise covered post-hospital extended care services furnished by an eligible SNF that has entered into a written agreement to partner with the ACO for purposes of this waiver. All other provisions of the statute and regulations regarding Medicare Part A post-hospital extended care services continue to apply.

We believe that clarity regarding whether a waiver applies to SNF services furnished to a particular beneficiary is important to help ensure compliance with the conditions of the waiver and also improve our ability to monitor waivers for misuse. Therefore, in the June 2015 final rule, we limited the waiver to ACOs in Track 3 because under the prospective assignment methodology used in Track 3, beneficiaries are assigned in advance to the ACO for the entire performance year (unless they meet any of the exclusion criteria under § 425.401(b) during the performance year), so it will be clearer to a Track 3 ACO whether the waiver applies to SNF services furnished to a particular beneficiary than it would be to an ACO in Track 1 or 2, where beneficiaries are assigned using a preliminary prospective assignment methodology with retrospective reconciliation (80 FR 32804). An ACO's use of the SNF 3-day rule waiver will be associated with a distinct and easily identifiable event, specifically, admission of a prospectively assigned beneficiary to a previously identified SNF affiliate without prior inpatient hospitalization or after an inpatient hospitalization of fewer than 3 days.

Based on our experiences under the Pioneer ACO Model, and in response to comments, we established certain requirements under § 425.612 for ACOs, ACO providers/suppliers, SNF affiliates, and beneficiaries with respect to the SNF 3-day rule waiver under the Shared Savings Program. All ACOs electing to participate in Track 3 will be offered the opportunity to apply for a waiver of the SNF 3-day rule for their prospectively assigned beneficiaries at the time of their initial application to participate in Track 3 of the program and annually thereafter while participating in Track 3. We anticipate accepting the first SNF 3-day rule waiver applications from Track 3 ACOs later this summer. As set forth at § 425.612(a)(1)(i), in their waiver applications, ACOs must demonstrate that they have the capacity to identify and manage beneficiaries who would be either directly admitted to a SNF or admitted to a SNF after an inpatient hospitalization of fewer than 3 days. As part of the application process, the ACO will be required to submit a list of the SNFs with which the ACO will partner (called "SNF affiliates") along with executed SNF affiliate agreements for each listed SNF. These SNF affiliates will be subject to program integrity screening under § 425.612(b). Additionally, the ACO must submit narratives describing how the ACO plans to implement the waiver, including the communication plan between the ACO and its SNF affiliates; a care management plan for beneficiaries admitted to a SNF affiliate; a beneficiary evaluation and admission plan approved by the ACO medical director and the healthcare professional responsible for the ACO's quality improvement and assurance processes; and a description of any financial relationships between the ACO, SNF, and acute care hospitals.

To be eligible to receive covered SNF services under the waiver, a beneficiary must be prospectively assigned to the ACO for the performance year in which he or she is admitted to the SNF affiliate, may not reside in a SNF or other long-term care setting, must be medically stable and have an identified skilled nursing or rehabilitation need that cannot be provided as an outpatient, and must meet the other requirements set forth at § 425.612(a)(1)(ii).

For a SNF to be eligible to partner with ACOs for purposes of the waiver, a SNF must have an overall quality rating of 3 or more stars under the CMS 5 Star Quality Rating System, must sign a written agreement with the ACO, which we refer to as the "SNF affiliate agreement," that includes elements determined by CMS, including: A clear indication of the effective dates of the SNF affiliate agreement; agreement to comply with Shared Savings Program rules, including but not limited to those specified in the participation agreement between the ACO and CMS; agreement to validate beneficiary eligibility to receive covered SNF services under the waiver prior to admission; remedial processes and penalties for noncompliance with the terms of the waiver, and other requirements set forth at § 425.612(a)(1)(iii). The SNF affiliate agreement must include these elements to ensure that the SNF affiliate understands its responsibilities related to implementation of the SNF 3-day rule waiver.

We indicated in the June 2015 final rule that the SNF 3-day rule waiver would be effective no earlier than January 1, 2017; thereafter, the waiver will be effective upon CMS notification to the ACO of approval for the waiver or the start date of the ACO's participation agreement, whichever is later, and will not extend beyond the term of the ACO's participation agreement. If CMS terminates the participation agreement under § 425.218, then the waiver will end on the date specified by CMS in the notice of termination. If the ACO terminates its participation agreement, then the waiver will end on the effective date of termination as specified in the written notification required under § 425.220.

We also indicated in the June 2015 final rule that we established the timeline for implementation of the SNF 3-day rule waiver to allow for development of additional subregulatory guidance, including necessary education and outreach for ACOs, ACO participants, ACO providers/suppliers, and SNF affiliates. We noted that we would continue to evaluate the waiver of the SNF 3-day rule, including further lessons learned from Innovation Center models in which a waiver of the SNF 3-day rule is being tested. We indicated that in the event we determined that additional safeguards or protections for beneficiaries or other changes were necessary, such as to incorporate additional protections for beneficiaries into the ACO's participation agreement or SNF affiliate agreements, we would propose the necessary changes through future rulemaking.

In considering additional beneficiary protections that may be necessary to ensure proper use of the SNF 3-day rule waiver under the Shared Savings Program, we note that there are existing, well established payment and coverage policies for SNF services based on sections 1861(i), 1862(a)(1), and 1879 of the Act that include protections for beneficiaries from liability for certain non-covered SNF charges. These existing payment and coverage policies for SNF services continue to apply to SNF services furnished to beneficiaries assigned to ACOs participating in the Shared Savings Program, including services furnished pursuant to the SNF 3-day rule waiver. (For example, see the Medicare Claims Processing Manual, Chapter 30—Financial Liability Protections, section 70, available at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c30.pdf*; Medicare Coverage of Skilled Nursing Facility Care beneficiary booklet, Section 6: Your Rights & Protections, available at *https://www.medicare.gov/Pubs/pdf/10153.pdf*; and Medicare Benefit Policy Manual, Chapter 8—Coverage of Extended Care (SNF) Services Under Hospital Insurance available at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c08.pdf*). In general, CMS requires that the SNF inform a beneficiary in writing about services and fees before the beneficiary is admitted to the SNF (§ 483.10(b)(6)); the beneficiary cannot be charged by the SNF for items or services that were not requested (§ 483.10(c)(8)(iii)(A)); a beneficiary cannot be required to request extra services as a condition of continued stay (§ 483.10(c)(8)(iii)(B)); and the SNF must inform a beneficiary that requests an item or service for which a charge will be made that there will be a charge for the item or service and what the charge will be (§ 483.10(c)(8)(iii)(C)). (See also section 6 of Medicare Coverage of Skilled Nursing Facility Care at *https://www.medicare.gov/Pubs/pdf/10153.pdf*.)

b. Proposals

Since publication of the June 2015 final rule, we have continued to learn from implementation and refinement of the SNF 3-day rule waiver in the Pioneer ACO Model (see *https://innovation.cms.gov/initiatives/Pioneer-aco-model/*) and the Next Generation ACO Model (see *https://innovation.cms.gov/initiatives/Next-Generation-ACO-Model*). Based on these experiences, we believe there are situations where it would be appropriate to require additional beneficiary financial protections under the SNF 3-day rule waiver for the Shared Savings Program. Specifically, we are concerned about potential beneficiary financial liability for non-covered Part A SNF services that might be directly related to use of the SNF 3-day rule waiver under the Shared Savings Program.

First, one example of a scenario under which a beneficiary may be at financial risk relates to the quarterly exclusions from a Track 3 ACO's prospective assignment list. For example, assume a beneficiary was prospectively assigned to a Track 3 ACO that has been approved for the SNF 3-day rule waiver (a waiver-approved ACO), but during the first quarter of the year, the beneficiary's Part B coverage terminated and the beneficiary is therefore no longer eligible to be assigned to the ACO. As a result, the beneficiary would be excluded from the ACO's prospective assignment list because the beneficiary meets one or more of the exclusion criteria specified at § 425.401(b). That is, although SNF services are covered under Part A, not Part B, the beneficiary would be dropped from the ACO's prospective assignment list if during the performance year the beneficiary is no longer enrolled in Part B and thus no longer eligible to be assigned to the ACO. We are concerned about some very limited situations, such as when a beneficiary's Part B coverage terminates during a quarter when the beneficiary is also receiving SNF services. The beneficiary may be admitted to a SNF without a prior 3-day inpatient hospital stay after his or her Part B coverage ended, but before the beneficiary appears on a quarterly exclusion list. It is not operationally feasible for CMS to notify the ACO and for the ACO, in turn, to notify its SNF affiliates, ACO participants, and ACO providers/suppliers immediately of the beneficiary's exclusion. The lag in communication may then cause the SNF affiliate to unknowingly admit a beneficiary who no longer qualifies for the waiver without a prior 3-day inpatient hospital stay. Absent specific beneficiary protections, we are concerned that the beneficiary could be charged for such non-covered SNF services. We do not believe it would be appropriate for CMS to hold the beneficiary or the SNF affiliate financially liable for such services. We believe we should allow for a reasonable amount of time for CMS to communicate beneficiary exclusions to an ACO and for the ACO to communicate the exclusions to its SNF affiliates, ACO participants, and ACO providers/suppliers. Typically there would be no way for the SNF affiliate to verify in real-time that a beneficiary continues to be prospectively assigned to the ACO; the SNF affiliate must rely upon the assignment list and quarterly exclusion lists provided by CMS to the ACO and communicated by the ACO to its SNF affiliates, ACO participants, and ACO providers/suppliers. Further, the beneficiary does not receive a notification regarding his or her eligibility for the SNF 3-day rule waiver prior to receiving SNF services under the waiver, so beneficiaries are not able to check their own eligibility.

To address delays in communicating beneficiary exclusions from the prospective assignment list, the Pioneer ACO Model and Next Generation ACO Model provide for a 90-day grace period that functionally acts as an extension of beneficiary eligibility for the SNF 3-day rule waiver and permits some additional time for the ACO to receive quarterly exclusions lists from CMS and communicate beneficiary exclusions to its SNF affiliates. We believe that it would be appropriate, in order to protect beneficiaries from potential financial liability related to the SNF 3-day rule waiver under the Shared Savings Program, to establish a similar 90-day grace period in the case of a beneficiary who was prospectively assigned to a waiver-approved ACO at the beginning of the performance year but is later excluded from assignment to the ACO.

Therefore, we believe it is necessary for purposes of carrying out the Shared Savings Program to allow these formerly assigned beneficiaries to receive covered SNF services under the SNF 3-day rule waiver when the beneficiary is admitted to a SNF affiliate within a 90-day grace period following the date that CMS delivers the quarterly beneficiary exclusion list to an ACO. The equitable and efficient implementation of the SNF 3-day rule waiver is necessary to further support ACOs' efforts to increase quality and decrease costs under two-sided performance-based risk arrangements. (See 80 FR 32804 for a detailed discussion of the rationale for establishing the SNF 3-day rule waiver). Based upon the experience in the Pioneer ACO Model, we believe it is not possible to adopt such a waiver without providing some protection for certain beneficiaries who were prospectively assigned to the ACO at the start of the year, but are subsequently excluded from assignment. Accordingly, we are proposing to modify the waiver to include a 90-day grace period to allow sufficient time for CMS to notify the ACO of any beneficiary exclusions, and for the ACO then to inform its SNF affiliates, ACO participants, and ACO providers/suppliers of those exclusions.

More specifically, we propose to modify the waiver under § 425.612(a)(1) to include a 90-day grace period that would permit payment for SNF services provided to beneficiaries who were initially on the ACO's prospective assignment list for a performance year but were subsequently excluded during the performance year. CMS would make payments for SNF services furnished to such a beneficiary under the terms of the SNF 3-day rule waiver if the following conditions are met:

- The beneficiary was prospectively assigned to a waiver-approved ACO at the beginning of the performance year but was excluded in the most recent quarterly exclusion list.
- The SNF affiliate services are furnished to a beneficiary admitted to the SNF affiliate within 90 days following the date that we deliver the quarterly exclusion list to the ACO.
- We would have otherwise made payment to the SNF affiliate for the services under the SNF 3-day rule waiver, but for the beneficiary's exclusion from the waiver-approved ACO's prospective assignment list.

We further note that we anticipate that there would be very few instances where it would be appropriate for SNF services to qualify for payment under this 90-day grace period. This is because this waiver only allows for payment for claims that meet all applicable requirements except the requirement for a prior 3-day inpatient hospital stay. For example, assume that a beneficiary who had been assigned to a waiver-approved ACO was admitted to a SNF without a prior 3-day inpatient hospital stay after his or her enrollment in an MA Plan, but before the beneficiary appears on a quarterly exclusion list. In this case, these SNF services would not be covered under FFS because the waiver does not expand coverage to include services furnished to Medicare beneficiaries enrolled in MA Plans. Both beneficiaries and healthcare providers are expected to know that the beneficiary is covered under an MA plan and not FFS Medicare.

Second, we are concerned that there could be other more likely scenarios where a beneficiary could be charged for non-covered SNF services that were a result of an ACO's or SNF's inappropriate use of the SNF 3-day rule waiver. Specifically, we are concerned that a beneficiary could be charged for non-covered SNF services if a SNF affiliate were to admit a FFS beneficiary who is not prospectively assigned to the waiver-approved ACO, and payment for SNF services is denied for lack of a qualifying inpatient hospital stay.

We believe this situation could occur as a result of a breakdown in one or more of processes the ACO and SNF affiliate are required to have in place to implement the waiver. For example, the SNF affiliate and the admitting ACO provider/supplier may not verify that the beneficiary appears on the ACO's prospective assignment list prior to admission, as required under the SNF 3-day rule waiver (§ 425.612(a)(1)(iii)(B)(4)) and the terms of the SNF's affiliate agreement with the ACO. In this scenario, Medicare would deny payment of the SNF claim under existing FFS rules because the beneficiary did not have a qualifying inpatient hospital stay. We are concerned that, once the claim is rejected, the beneficiary may not be protected from financial liability, and thus could be charged by the SNF affiliate for these non-covered SNF services that were a result of an inappropriate attempt to use the waiver, potentially subjecting the beneficiary to significant financial liability. However, in this scenario, a SNF with a relationship to the ACO submitted the claim that was rejected for lack of a qualifying inpatient hospital stay, but that otherwise would have been paid by Medicare. In this circumstance, we propose to assume the SNF's intent was to rely upon the SNF 3-day waiver, but the waiver requirements were not met. We believe it is reasonable to assume the SNF's intent was to use the SNF 3-day rule waiver because, as a SNF affiliate, the SNF should be well aware of the ability to use the SNF 3-day rule waiver and, by submitting the claim, demonstrated an expectation that CMS would pay for SNF services that would otherwise have been rejected for lack of a 3-day inpatient hospital stay. We believe that in this scenario, the rejection of the claim under the SNF 3-day rule waiver could easily have been avoided if the ACO, the admitting ACO provider/supplier, and the SNF affiliate had confirmed that the requirements for use of the SNF 3-day rule waiver were satisfied. Because each of these entities is in a better position to know the requirements of the waiver and ensure that they are met than the beneficiary is, we believe that the ACO and/or the SNF affiliate should be accountable for such rejections and the SNF affiliate should be prevented from attempting to charge the beneficiary for the non-covered SNF stay.

To address situations similar to this scenario where the beneficiary may be subject to financial liability due to an eligible SNF submitting a claim that is not paid only as a result of the lack of a qualifying inpatient hospital stay, the Next Generation ACO Model generally places the financial responsibility on the SNF, where the SNF knew or reasonably could be expected to have known that payment would not be made for the non-covered SNF services. In such cases, CMS makes no payment for the services and the SNF may not charge the beneficiary for the services and must return any monies collected from the beneficiary. Additionally, under the Next Generation ACO Model, the ACO must indemnify and hold the beneficiary harmless for payment for the services. We believe it is appropriate to propose to adopt a similar policy under the Shared Savings Program because, under § 425.612(a)(1)(iii)(B), to be a SNF affiliate, a SNF must agree to validate the eligibility of a beneficiary to receive covered SNF services in accordance with the waiver prior to admission to the SNF, and otherwise comply with the requirements and conditions of the Shared Savings Program. SNF affiliates are required to be familiar with the SNF 3-day rule and the terms and conditions of the SNF 3-day rule waiver for the Shared Savings Program, and should know to verify that a FFS Medicare beneficiary who is a candidate for admission has completed a qualifying hospital stay or that the admission meets the criteria under a waiver of the SNF 3-day rule that is properly in place. Additionally, ACOs and their SNF affiliates are required to develop plans that will govern communication and beneficiary evaluation and admission prior to use of the SNF 3-day rule waiver. In these circumstances, we believe it is reasonable that the ultimate responsibility and liability for a non-covered SNF admission should rest with the admitting SNF affiliate.

Therefore, to protect FFS beneficiaries from being charged in certain circumstances for non-covered SNF charges related to the waiver of the SNF 3-day rule under the Shared Savings Program, potentially subjecting such beneficiaries to significant financial liability, we are proposing to add certain beneficiary protection requirements in § 425.612(a)(1). These requirements would apply to SNF services furnished by a SNF affiliate that would otherwise have been covered except for the lack of a qualifying hospital stay preceding the admission to the SNF affiliate. Specifically, we propose that we would make no payment to the SNF, and the SNF may not charge the beneficiary for the non-covered SNF services, in the event that a SNF that is a SNF affiliate of a Track 3 ACO that has been approved for the SNF 3-day rule waiver admits a FFS beneficiary who was never prospectively assigned to the waiver-approved ACO (or was assigned but later excluded and the 90 day grace period has lapsed), and the claim is rejected only for lack of a qualifying inpatient hospital stay.

In this situation, we propose that we would apply the following rules:

- We would make no payment to the SNF affiliate for such services.
- The SNF affiliate must not charge the beneficiary for the expenses incurred for such services; and the SNF affiliate must return to the beneficiary any monies collected for such services.
- The ACO may be required to submit a corrective action plan to CMS for approval as specified at § 425.216(b) addressing what actions the ACO will take to ensure that the SNF 3-day rule waiver is not misused in the future. If after being given an opportunity to act upon the corrective action plan the ACO fails to come into compliance, approval to use the waiver will be terminated in accordance with § 425.612(d). We note that in accordance with our existing program rules at §§ 425.216 and 425.218, CMS retains the authority to take corrective action, including terminating an ACO for non-compliance with program rules. A misuse of a waiver under § 425.612 would constitute non-compliance with program rules. Accordingly, we propose to codify at new provision § 425.612(d)(4) that misuse of a waiver under § 425.612 may result in CMS taking remedial action against the ACO under §§ 425.216 and 425.218, up to and including termination of the ACO from the Shared Savings Program.

We propose that if the SNF submitting the claim is a SNF affiliate for a waiver-approved ACO, and the only reason for the rejection of the claim is lack of a qualifying inpatient hospital stay, then CMS would assume the SNF intended to rely upon the SNF 3-day rule waiver. We would not assume the SNF intended to rely upon the SNF 3-day rule waiver if the SNF is not a SNF affiliate of a waiver-approved ACO because the waiver is not available to SNFs more broadly. We believe intended reliance on the waiver is an important factor in determining whether the additional beneficiary protections proposed here should apply as explained above. Outside the context of an intent to rely on the SNF 3-day rule waiver, we do not believe it would be necessary to include additional beneficiary protections under the Shared Savings Program because there is no reason for either the beneficiary or the SNF to expect that different coverage rules would apply to SNF services. In these other situations, the beneficiary protections generally applicable under traditional FFS Medicare, noted earlier in this section, continue to apply.

As previously noted in this section, we anticipate accepting the first SNF 3-day rule waiver applications from Track 3 ACOs later this summer. We strongly believe it is important to ensure that beneficiaries have appropriate financial protections against misuse of the waiver prior to approving any SNF 3-day rule waiver applications. We also recognize that ACOs and their SNF affiliates could be reluctant to enter into a SNF affiliate agreement without there being clarity as to their potential responsibility for non-covered SNF services related to the waiver. For these reasons, although we will still accept applications from Track 3 ACOs for the SNF 3-day rule waiver later this summer, in the event we finalize any of the proposed beneficiary protections in the CY 2017 PFS final rule with comment period, we plan to develop a process for ACOs to confirm that they and their SNF affiliates agree to comply with all requirements related to the SNF 3-day rule waiver, including any new requirements adopted in this rulemaking. ACOs and SNF affiliates that do not agree to comply with all requirements would be ineligible for the SNF 3-day rule waiver. We note that this confirmation process may delay approval of ACOs' applications for the SNF 3-day rule waiver; however, we do not anticipate approval would be delayed beyond the first quarter of 2017.

We seek comments on these proposals. We note that under our proposed beneficiary protection provision, a SNF affiliate would be prohibited from charging a beneficiary for non-covered SNF services even in cases where the beneficiary explicitly requested or agreed to being admitted to the SNF in the absence of a qualifying 3-day hospital stay if all other requirements for coverage are met. We therefore specifically seek comment on whether it is reasonable to hold SNFs that are SNF affiliates responsible for all claims that are rejected solely as a result of lack of a qualifying inpatient hospital stay. We also seek comment on whether the ACO rather than or in addition to the SNF affiliate, should be held liable for such claims and under what circumstances. We also seek comment on our proposal to modify the waiver under § 425.612(a)(1) to include a 90-day grace period for beneficiaries prospectively assigned to a waiver-approved ACO at the start of the performance year but later excluded. We seek comment on the proposed length of the grace period, and in particular whether the grace period should be less than 90 days, given our expectation that ACOs will share the quarterly beneficiary exclusion lists with their SNF affiliates, ACO participants, and ACO providers/suppliers in a timely manner. Finally, we seek comment on any other related issues that we should consider in connection with these proposals to protect beneficiaries from significant financial liability for non-covered SNF services related to the waiver of the SNF 3-day rule under the Shared Savings Program.

4. Technical Changes

a. Financial Reconciliation for ACOs That Fall Below 5,000 Assigned Beneficiaries

Section 1899(b)(2)(D) of the Act includes a requirement that a participating ACO must have a minimum of 5,000 Medicare FFS beneficiaries assigned to it. Currently, the regulations at § 425.110(b) indicate that if at any time during the performance year, an ACO's assigned population falls below 5,000, the ACO may be subject to the actions described in §§ 425.216 and 425.218; the regulations further indicate at § 425.110(b)(1) that while under a CAP, the ACO remains eligible for shared savings and losses and the MSR and MLR (if applicable) is set "at a level consistent with the number of assigned beneficiaries." We have applied this rule in the past to perform financial reconciliation for ACOs that fell below 5,000 assigned beneficiaries. In these cases, the ACO was subject to a CAP and financial reconciliation was based on a variable MSR/MLR that was determined by the number of assigned beneficiaries. For example, we have calculated the ACO's MSR based on an expanded sliding scale that include a range of 3,000 to 4,999 assigned beneficiaries with a corresponding MSR range of 5.0 to 3.9 percent.

However, ACOs under risk-based tracks are not limited to financial reconciliation under a variable MSR/MLR that is based on the number of assigned beneficiaries. In the June 2015 final rule (see 80 FR 32769– 32771, and 32779–32780), we finalized a policy that provides ACOs under two-sided performance-based risk tracks with an opportunity to choose among several options for establishing their MSR/MLR. In addition to being able to choose a symmetrical MSR/MLR that varies based on the ACO's number of assigned beneficiaries, ACOs under two-sided performance-based risk tracks can also choose from a menu of non-variable MSR/MLR options (either a 0 percent MSR/MLR or a symmetrical MSR/MLR in a 0.5 percent increment between 0.5 through 2.0 percent).

We believe it is important to clarify the policy regarding situations where an ACO under a two-sided performance-based risk track has chosen a non-variable MSR/MLR at the start of the agreement period but has fallen below 5,000 assigned beneficiaries at the time of financial reconciliation. As discussed in detail in the June 2015 final rule, we continue to believe that ACOs under two-sided performance-based risk tracks are best positioned to determine the level of risk that they are prepared to accept. Therefore, we are proposing to update the regulations at § 425.110(b)(1) to be consistent with the regulatory changes in the June 2015 final rule that permit ACOs under a two-sided performance-based risk track (Track 2 and Track 3) to choose their own MSR/MLR from a menu of options. Specifically, we are proposing to update the regulations at § 425.110(b)(1) to indicate that in the event an ACO falls below 5,000 assigned beneficiaries at the time of financial reconciliation, the ACO participating under a two-sided risk track will be eligible to share in savings (or losses) and the MSR/MLR will be set at a level consistent with the choice of MSR/MLR that the ACO made at the start of the agreement period. If the Track 2 or Track 3 ACO selected a symmetrical MSR/MLR option based on a fixed percentage (for example, zero percent or a percentage between 0.5 and 2 percent) regardless of ACO size, then the current methodology for use of a variable MSR/MLR based on the ACO's number of assigned beneficiaries would not apply. For example, if at the beginning of the agreement period the ACO chose a 1.0 percent MSR/MLR and the ACO's assigned population falls below 5,000, the MSR/MLR will remain 1.0 percent for purposes of financial reconciliation while the ACO is under a CAP. Further, as we noted in earlier rulemaking, if the ACO has elected a variable MSR/MLR, the methodology for calculating the variable MSR/MLR under a two-sided model is consistent with the methodology for calculating the variable MSR that is required under the under the one-sided model (Track 1) (see 80 FR 32769 through 32771; 32779 through 32780). Under the one-sided shared savings model (Track 1), we have accounted for circumstances where an ACO's number of assigned beneficiaries falls below 5,000, by expanding the variable MSR range based on input from the CMS Office of the Actuary (OACT). Thus, in the case where a Track 2 or Track 3 ACO selects a variable MSR/MLR based on its number of assigned beneficiaries, and the ACO's number of assigned beneficiaries falls below 5,000, we would continue to use an approach for determining the MSR/MLR range consistent with the approach for calculating the MSR range under the one-sided model.

b. Requirements for Merged or Acquired TINs

ACOs frequently request that we take into account the claims billed by the TINs of practices that have been acquired by sale or merger for the purpose of meeting the minimum assigned beneficiary threshold, establishing a more accurate financial benchmark, and determining the prospective or preliminary prospective assignment list for the upcoming performance year. In response to these inquiries, we initially developed subregulatory guidance that allowed claims billed under the TIN of a merged or acquired entity to be considered in certain circumstances. In that guidance we indicated that the merged or acquired entity's TIN may no longer be used to bill Medicare. In the June 2015 final rule, we codified the policies outlined in this guidance allowing for consideration of claims billed under merged or acquired entities' TINs for purposes of beneficiary assignment and establishing the ACO's benchmark, provided certain requirements were met (§§ 425.204(g), 425.118(a)(2)). However, the regulation at § 425.204(g) indicates that an ACO may request that CMS consider, for purposes of beneficiary assignment and establishing the ACO's benchmark under § 425.602, claims billed by "Medicare-enrolled" entities' TINs that have been acquired through sale or merger by an ACO participant. Because the regulation at § 425.204(g) refers to such merged or acquired TINs as "Medicare-enrolled," we have received inquiries from ACOs regarding whether such merged or acquired TINs must continue to be Medicare-enrolled after the merger or acquisition has been completed and the TINs are no longer used to bill Medicare.

It was not our intent to establish such a requirement. We do not believe there would be a program purpose to require the TIN of a merged or acquired entity to maintain Medicare enrollment if it is no longer used to bill Medicare. Therefore, to address this issue, we are proposing a technical change to § 425.204(g) to clarify that the merged/acquired TIN is not required to remain Medicare enrolled after it has been merged or acquired and no longer used to bill Medicare.

L. Value-Based Payment Modifier and Physician Feedback Program

1. Overview

Section 1848(p) of the Act requires that we establish a value-based payment modifier (VM) and apply it to specific physicians and groups of physicians the Secretary determines appropriate starting January 1, 2015, and to all physicians and groups of physicians by January 1, 2017. On or after January 1, 2017, section 1848(p)(7) of the Act provides the Secretary discretion to apply the VM to eligible professionals (EPs) as defined in section 1848(k)(3)(B) of the Act. Section 1848(p)(4)(C) of the Act requires the VM to be budget neutral. The VM and Physician Feedback program continue CMS' initiative to recognize and reward clinicians based on the quality and cost of care provided to their patients, increase the transparency of health care quality information and to assist clinicians and beneficiaries in improving medical decision-making and health care delivery. As stated in the CY 2016 PFS final rule with comment period (80 FR 71277), the MACRA was enacted on April 16, 2015. Under section 1848(p)(4)(B)(iii) of the Act, as amended by section 101(b)(3) of MACRA, the VM shall not be applied to payments for items and services furnished on or after January 1, 2019. Section 1848(q) of the Act, as added by section 101(c) of MACRA, establishes the Merit-based Incentive Payment System (MIPS) that shall apply to payments for items and services furnished on or after January 1, 2019.

2. Overview of Existing Policies for the VM

In the CY 2013 PFS final rule with comment period, we discussed the goals of the VM and also established that specific principles should govern the implementation of the VM (77 FR 69307). We refer readers to that rule for a detailed discussion. In the CY 2013 PFS final rule with comment period (77 FR 69310), we finalized policies to phase-in the VM by applying it beginning January 1, 2015, to Medicare PFS payments to physicians in groups of 100 or more EPs. A summary of the existing policies that we finalized for the CY 2015 VM can be found in the CY 2014 PFS proposed rule (78 FR 43486 through 43488). Subsequently, in the CY 2014 PFS final rule with comment period (78 FR 74765 through 74787), we finalized policies to continue the phase-in of the VM by applying it starting January 1, 2016, to payments under the Medicare PFS for physicians in groups of 10 or more EPs. Then, in the CY 2015 PFS final rule with comment period (79 FR 67931 through 67966), we finalized policies to complete the phase-in of the VM by applying it starting January 1, 2017, to payments under the Medicare PFS for physicians in groups of 2 or more EPs and to physician solo practitioners. In the CY 2016 PFS final rule with comment period (80 FR 71277 through 71279), we finalized that in the CY 2018 payment adjustment period, the VM will apply to nonphysician EPs who are physician assistants (PAs), nurse practitioners (NPs), clinical nurse specialists (CNSs), and certified registered nurse anesthetists (CRNAs) in groups with 2 or more EPs and to PAs, NPs, CNSs, and CRNAs who are solo practitioners.

3. Provisions of This Proposed Rule

As a general summary, we are proposing to update the VM informal review policies and establish how the quality and cost composites under the VM would be affected for the CY 2017 and CY 2018 payment adjustment periods in the event that unanticipated program issues arise.

a. Expansion of the Informal Inquiry Process To Allow Corrections for the VM

Section 1848(p)(10) of the Act provides that there shall be no administrative or judicial review under section 1869 of the Act, section 1878 of the Act, or otherwise of the following:

- The establishment of the VM.
- The evaluation of the quality of care composite, including the establishment of appropriate measures of the quality of care.
- The evaluation of the cost composite, including the establishment of appropriate measures of costs.
- The dates of implementation of the VM.
- The specification of the initial performance period and any other performance period.
- The application of the VM.
- The determination of costs.

These statutory requirements regarding limitations of review are reflected in § 414.1280. We previously indicated in the CY 2013 PFS final rule with comment period (77 FR 69326) that we believed an informal review mechanism is appropriate for groups of physicians to review and to identify any possible errors prior to application of the VM, and we established an informal inquiry process at § 414.1285.

In the CY 2015 PFS final rule with comment period (79 FR 67960), for the CY 2015 payment adjustment period, we finalized: (1) A February 28, 2015 deadline for a group to request correction of a perceived error made by CMS in the determination of its VM; and (2) a policy to classify a TIN as "average quality" in the event we determined that we have made an error in the calculation of the quality composite. Beginning with the CY 2016 payment adjustment period: (1) We finalized a deadline of 60 days that would start after the release of the Quality and Resource Use Reports (QRURs) for the applicable performance period for a group or solo practitioner to request a correction of a perceived error related to the VM calculation, and (2) we stated we would take steps to establish a process for accepting requests from physicians to correct certain errors made by CMS or a third-party vendor (for example, PQRS-qualified registry). Our intent was to design this process as a means to recompute a TIN's quality composite and/or cost composite in the event we determine that we initially made an erroneous calculation. We noted that if the operational infrastructure was not available to allow this recomputation, we would continue the approach for the CY 2015 payment adjustment period to classify a TIN as "average quality" in the event we determine that we have made an error in the calculation of the quality composite. We finalized that we would recalculate the cost composite in the event that an error was made in the cost composite calculation. We noted that we would provide additional operational details as necessary in subregulatory guidance.

Moreover, for both the CY 2015 payment adjustment period and future adjustment periods, we finalized a policy to adjust a TIN's quality-tier if we make a correction to a TIN's quality and/or cost composites because of this correction process. We further noted that there is no administrative or judicial review of the determinations resulting from this expanded informal inquiry process under section 1848(p)(10) of the Act. In the CY 2015 PFS final rule for the CY 2016 payment adjustment period, we noted that if the operational infrastructure is not available to allow the recomputation of quality measure data we would continue the approach of the initial corrections process to classify a TIN as "average quality" in the event we determine a third-party vendor error or CMS made an error in the calculation of the quality composite.

In the CY 2016 PFS final rule with comment period (80 FR 71294 through 71295), for the CY 2017 and CY 2018 payment adjustment periods, we finalized a deadline of 60 days that would start after the release of the QRURs for the applicable performance period for a group or solo practitioner to request a correction of a perceived error related to the VM calculation. We also finalized the continuation of the process for accepting requests from groups and solo practitioners to correct certain errors made by CMS or a third-party vendor (for example, PQRS-qualified registry). We stated we would continue the approach of the initial corrections process to classify a TIN as "average quality" in the event we determine a third-party vendor error or CMS made an error in the calculation of the quality composite and the infrastructure was not available to allow for recomputation of the quality measure data. Additionally, we finalized that we would reclassify a TIN as Category 1 when PQRS determines on informal review that at least 50 percent of the TIN's EPs meet the criteria to avoid the PQRS downward payment adjustment for the relevant payment adjustment year. If the group was initially classified as Category 2, then we would not expect to have data for calculating their quality composite, in which case they would be classified as "average quality"; however, if the data is available in a timely manner, then we would recalculate the quality composite.

As a result of issues that we became aware of prior to and during the CY 2016 VM informal review process that are discussed below, we have learned that re-running QRURs and recalculating the quality composite is not always practical or possible, given the diversity and magnitude of the errors, timing of when we become aware of an error, and practical considerations in needing to compute a final VM upward payment adjustment factor after the performance period has ended based on the aggregate amount of downward payment adjustments. Furthermore, this approach can create uncertainty for groups and solo practitioners about their final VM payment adjustment making it difficult for them to plan and make forecasts.

- *Electronic Health Record (EHR) and Qualified Clinical Data Registry (QCDR) Issues:* CMS was unable to determine the accuracy of PQRS data submitted via EHR and QCDR for the CY 2014 performance period due to data integrity issues. Consequently, if a group (as identified by its Medicare Taxpayer Identification Number (TIN)) or the EPs in a group reported PQRS measures *only* through the EHR or QCDR reporting mechanism, then the TIN's quality composite score for the CY 2016 VM was based on the TIN's performance on the CMS-calculated quality outcome measures and the Consumer Assessment of Healthcare Providers and Systems (CAHPS) for PQRS survey measures (if applicable). If a TIN was classified as "low quality" based on its performance on these measures, then we reclassified the TIN as "average quality." If the TIN's initial quality tier designation was "average quality" or "high quality", then that quality tier designation was retained. Without the additional PQRS data submitted via EHR and QCDR, we were concerned that a low quality designation based on the three CMS-calculated quality outcome measures and CAHPS for PQRS survey measures (if applicable) may not necessarily represent a TIN's quality performance If the TIN also reported PQRS measures for the CY 2014 performance period through reporting mechanisms other than EHR or QCDR, then those PQRS quality measures, along with CMS-calculated quality outcome measures, and CAHPS for PQRS survey measures (if applicable), were used to calculate the TIN's quality composite score for the CY 2016 VM.
- *Incomplete Claims Identification Issue:* After the release of the 2014 Annual QRURs in September 2015, we discovered a defect in the program used to identify the claims from CY 2014, which is the performance period for the VM CY 2016 payment adjustment period: Only claims from January 12 through December 31 were identified; claims from January 1 through January 11 were incorrectly omitted from 2016 VM calculations. These missing claims accounted for 2.73 percent of the CY 2014 claims. We re-ran all of the 2014 annual QRURs to correct this issue, including recalculating benchmarks and standard deviations for the cost measures to avoid disadvantaging groups as a result of using artificially low cost benchmarks. Of the approximately 13,800 TINs subject to the CY 2016 VM, 28 TINs received a lower VM and 8 TINs received a higher VM. There were also 27 TINs newly subject to the CY 2016 VM. Out of these 27 TINs, 12 were classified as Category 1 TINs and 15 were classified as Category 2 TINs. TINs were not held harmless from a lower VM resulting from these corrections. We notified the TINs that were affected by this issue.
- *Specialty Adjustment Issue:* In the course of performing quality assurance for the 2015 Mid-Year QRURs, we discovered a defect in the program used to specialty-adjust the cost measures. As a result of this defect, we determined that the CY 2016 VM for 28 TINs (out of approximately 13,800 TINs subject to the CY 2016 VM) were incorrectly calculated. Holding the benchmarks for the cost measures and the mean cost

composite score constant, 8 TINs would have had a lower VM and 20 TINs would have had a higher VM in CY 2016. We corrected the cost composite designation for the 20 TINs whose CY 2016 VM was higher after the recalculation and left the original cost composite designation for the 8 TINs whose VM was adversely affected by the recalculation.

Due to the volume and complexities of the informal review issues, the inconsistency of available PQRS data to calculate a TIN's quality composite, the case-by-case nature of the informal review process, and the condensed timeline to calculate an accurate VM upward payment adjustment factor, we believe that we need to update the VM informal review policies and establish in rulemaking how the quality and cost composites under the VM would be affected if unanticipated issues arise (for example, the program issues described above, errors made by a third-party such as a vendor, or errors in our calculation of the quality and/or cost composites). The intent of these proposals are not to provide relief for EPs and groups who fail to report under PQRS, but rather to provide a mechanism for addressing unexpected issues such as the data integrity issues discussed above.

Recalculating the quality composite is operationally complex, and does not align with the current timeline given the volume of informal reviews and the need to calculate the VM upward payment adjustment factor as close to the beginning of the payment adjustment period as possible. We want to close out as many informal reviews as possible before the VM upward payment adjustment factor is calculated, to lend confidence to the adjustment factor and to provide finality for the clinicians, and to minimize claims reprocessing. Limiting the potential movement of TINs between VM quality tiers based on informal review may result in a more accurate adjustment factor calculation and provide greater predictability for the CMS' Office of the Actuary (OACT) in making assumptions around the adjustment factor including assumptions around the impact of outstanding informal reviews at the time of the calculations. We believe that our proposals would help groups and solo practitioners to better predict the outcome of their final VM adjustment and reduce uncertainty as we continue to improve our systems.

Table 38 summarizes our proposals.

TABLE 38—PROPOSED QUALITY AND COST COMPOSITE STATUS FOR TINs DUE TO INFORMAL REVIEW DECISIONS AND WIDESPREAD QUALITY AND COST DATA ISSUES

	Scenario 1: TINS moving from Category 2 to Category 1 as a result of PQRS or VM informal review process		Scenario 2: Non-GPRO Category 1 TINs with additional EPs avoiding PQRS payment adjustment as a result of PQRS informal review process		Scenario 3: Category 1 TINs with widespread quality data issues		Scenario 4: Category 1 TINs with widespread claims data issues	
	Initial composite	Revised composite	Initial composite	Revised composite	Initial composite	Revised composite	Recalculated composite	Revised composite
Quality	N/A	Average	Low	Average	N/A	Average	Low	Average.
	N/A	Average	Average	Average	N/A	Average	Average	Average.
	N/A	Average	High	High	N/A	Average	High	High.
Cost	Low	Low	Low	Low	Low	Low	Low	Low.
	Average	Average	Average	Average	Average	Average	Average	Average.
	High	Average	High	High	High	Average	High	Average.

Scenario 1: TINs Moving From Category 2 to Category 1 as a Result of PQRS or VM Informal Review Process

For the CY 2017 VM, Category 1 will include those groups that meet the criteria to avoid the CY 2017 PQRS payment adjustment as a group practice participating in the PQRS Group Practice Reporting Option (GPRO) in CY 2015 and groups that have at least 50 percent of the group's EPs meet the criteria to avoid the CY 2017 PQRS payment adjustment as individuals (80 FR 71280). Category 1 also includes those solo practitioners that meet the criteria to avoid the CY 2017 PQRS payment adjustment as individuals. Category 2 will include groups and solo practitioners that are subject to the CY 2017 VM and do not fall within Category 1 (79 FR 67939). We finalized a similar two-category approach for the CY 2018 VM based on participation in the PQRS by groups and solo practitioners in 2016 (80 FR 71280 through 71281).

If a TIN is initially classified as Category 2, and subsequently, through the PQRS or VM informal review process, the TIN is classified as Category 1 then we propose to classify the TIN's quality composite as "average quality" instead of attempting to calculate the quality composite. We also propose to calculate the TIN's cost composite using the quality-tiering methodology. If the TIN is classified as "high cost" based on its performance on the cost measures, then we propose to reclassify the TIN's cost composite as "average cost." If the TIN is classified as "average cost" or "low cost", then we propose that the TIN would retain the calculated cost tier designation. We note that in the CY 2016 PFS final rule with comment period (80 FR 71280), we finalized a policy for the CY 2017 and 2018 payment adjustment periods that when determining whether a group will be included in Category 1, we will consider whether the 50 percent threshold has been met regardless of whether the group registered to participate in the PQRS GPRO for the relevant performance period. We believe this policy will allow groups that register for a PQRS GPRO, but fail as a group to meet the criteria to avoid the PQRS payment adjustment an additional opportunity for the quality data reported by individual EPs in the group to be taken into account for the purposes of applying the VM. Consequently, because of this policy we anticipate that the number of TINs who could fall into Scenario 1 would be minimal; however, we believe it is necessary to have a policy in the event that CMS determines on informal review that Category 2 TINs were negatively impacted by a third-party vendor error or CMS made an error in the calculation of the quality composite. We propose to apply these policies for the CY 2017 VM and CY 2018 VM.

Calculating the quality composite for a TIN that was initially classified as Category 2 would be operationally complex given the timeline for determining and applying the VM adjustments for all TINs subject to the VM, the volume of informal reviews, the need to calculate the VM upward payment adjustment factor as close to the beginning of the payment adjustment period as possible, and uncertainty about the availability of the

PQRS quality data. Therefore, classifying the quality composite as "average quality" would offer a predictable decision for all informal reviews where a TIN changes classification from Category 2 to Category 1.

Our proposal to calculate the cost composite and assign "average cost" if the cost composite is initially classified as "high cost" would alleviate concerns from stakeholders that a TIN may receive a downward VM payment adjustment under the quality-tiering methodology as a result of being classified as average quality and high cost. Under our proposal discussed above, for TINs in Scenario 1, we would not consider a TIN's actual performance on the quality measures or calculate a quality composite score; rather, we would classify the TIN's quality composite as average quality for the reasons stated above. In this scenario, we do not believe that we should retain a TIN's "high cost" designation when the TIN's actual cost performance is not being compared to the TIN's actual quality performance, as it is possible the TIN might have scored high quality if actual performance had been considered. We believe that these proposals would help groups and solo practitioners to better predict the outcome of their final VM adjustment and reduce uncertainty about the impact of the informal review. Additionally, it is important to note that groups or solo practitioners who submit an informal review request would not automatically be covered by the policy proposed for Scenario 1. We would verify on informal review that the group or solo practitioner did submit complete and accurate data and did meet the criteria to avoid the PQRS payment adjustment to be included in Category 1.

We request comments on these proposals.

Scenario 2: Non-GPRO Category 1 TINs With Additional EPs Avoiding PQRS Payment Adjustment as a Result of PQRS Informal Review Process

For the CY 2017 VM, Category 1 will include groups that have at least 50 percent of the group's EPs meet the criteria to avoid the CY 2017 PQRS payment adjustment as individuals (80 FR 71280). A similar policy was finalized for the CY 2018 VM (80 FR 71280). If a TIN is classified as Category 1 for the CY 2017 VM by having at least 50 percent of the group's EPs meet the criteria to avoid the CY 2017 PQRS payment adjustment as individuals, and subsequently, through the PQRS informal review process, it is determined that additional EPs that are in the TIN also meet the criteria to avoid the CY 2017 PQRS payment adjustment as individuals, then we propose the following policies to determine the TIN's quality and cost composites:

- If the TIN's quality composite is initially classified as "low quality", then we propose to reclassify the TIN's quality composite as "average quality." If the TIN's quality composite is initially classified as "average quality" or "high quality", then we propose that the TIN would retain that quality tier designation.
- We would maintain the cost composite that was initially calculated.

We propose to apply these policies for the CY 2017 VM and CY 2018 VM. Under these policies, we would not recalculate the TIN's quality composite to include the additional EPs that were determined to have met the criteria to avoid the PQRS payment adjustment as individuals through the PQRS informal review process. As discussed under Scenario 1, recalculating the quality composite is operationally complex, and we may not have PQRS data for the additional EPs because they did not meet the criteria to avoid the PQRS payment adjustment during the initial determination. In addition, we seek to avoid a situation where by recalculating the quality composite, a TIN may be subject to a lower quality tier designation because a few EPs in the TIN independently pursued PQRS informal reviews. As stated above, we are proposing to reclassify a TIN's quality composite as average quality if it is initially classified as "low quality" in order to avoid a situation where we do not have the PQRS quality data for those few EPs whose quality performance could have bumped the TIN up from a low quality designation as the EPs did not meet the criteria to avoid the PQRS payment adjustment during the initial determination. Additionally, it is important to note that TINs whose EPs submit an informal review request would not automatically be covered by the policy proposed for Scenario 2. We would verify on informal review that an EP did submit complete and accurate data and did meet the criteria to avoid the PQRS payment adjustment as an individual in order for the TIN to be included in Category 1.

We request comments on these proposals.

Scenario 3: Category 1 TINs With Widespread Quality Data Issues

In cases where there is a systematic issue with any of a Category 1 TIN's quality data that renders it unusable for calculating a TIN's quality composite, we propose to classify the TIN's quality composite as average quality. For this proposal, we consider widespread quality data issues, as issues that impact multiple TINs and we are unable to determine the accuracy of the data submitted via these TINs (for example, the EHR and QCDR issues for the CY 2014 performance period as described above). This proposal would offer a predictable designation for all TINs under this scenario.

We also propose to calculate the TIN's cost composite using the quality-tiering methodology. If the TIN is classified as "high cost" based on its performance on the cost measures, then we propose to reclassify the TIN's cost composite as "average cost." If the TIN is classified as "average cost" or "low cost", then we propose that the TIN would retain the calculated cost tier designation. We propose to apply these policies for the CY 2017 VM and CY 2018 VM.

As discussed under Scenario 1, our proposal to calculate the cost composite and assign "average cost" if the cost composite is initially classified as "high cost" would alleviate concerns from stakeholders that a TIN may receive a downward VM payment adjustment under the quality-tiering methodology as a result of being classified as average quality and high cost. Similarly, for TINs in Scenario 3, we would not consider a TIN's actual performance on the quality measures or calculate a quality composite score; rather, we would classify the TIN's quality composite as average quality for the reasons stated above. In this scenario, we do not believe that we should retain a TIN's high cost designation when the TIN's actual cost performance is not being compared to the TIN's actual quality performance, as it is possible the TIN might have scored high quality if actual performance had been considered. We would continue to show and designate these groups as high cost in their annual QRURs so they have the opportunity to understand and improve their performance, but under our proposal, we would classify their cost composite as average cost for purposes of determining their VM adjustment. Additionally, it is important to note that groups or solo practitioners would only be covered by the policy proposed for Scenario 3 once we verify that the group or solo practitioner did submit complete and accurate data and did meet the criteria to avoid the PQRS payment adjustment in order to be included in Category 1.

We request comments on these proposals.

Further, we note that we expect quality data issues such as these to be significantly limited moving forward. We have included new front-end edits to the data submission process to catch errors that result in such quality data issues early enough to be corrected. Additionally, we note that TINs are ultimately responsible for the data that are submitted by their third-party vendors and expect that TINs are holding their vendors accountable for accurate reporting. While we understand that data submission requirements are evolving and that both vendors and CMS are developing capabilities for reporting and assessing performance, we are considering further policies to promote complete and accurate reporting by registries and other third-party entities that submit data on behalf of groups and EPs.

Scenario 4: Category 1 TINs With Widespread Claims Data Issues

If we determine after the release of the Quality and Resource Use Reports (QRURs) that there is a widespread claims data issue that impacts the calculation of the quality and/or cost composites for Category 1 TINs, we propose to recalculate the quality and cost composites for affected TINs. For this proposal, we consider widespread claims data issues, as issues that impact multiple TINs and require the recalculation of the quality and/or cost composites (for example, the incomplete claims identification and specialty adjustment issues described above).

After recalculating the composites, if the TIN's quality composite is classified as low quality, then we propose to reclassify the quality composite as average quality, and conversely, if the TIN's cost composite is classified as high cost, we propose to reclassify the cost composite as average cost. If the TIN is classified as average quality, high quality, average cost or low cost, then we propose that the TIN would retain the calculated quality or cost tier designation. We are proposing to assign average quality if the quality composite is classified as low quality and assign average cost if the cost composite is classified as high cost after recalculating the quality and cost composites because, after a claims data issue is identified, it would take approximately 6 weeks to recalculate the composites and notify groups and solo practitioners about their recalculated VM. Given that the VM informal review period lasts for 60 days after the release of the QRURs and the timing of when we become aware of an error, we would likely not be able to notify groups and solo practitioners about their recalculated VM before the end of the informal review period. We believe these proposed policies are necessary to provide certainty for groups and solo practitioners about their final VM payment adjustment and due to the condensed timeline to calculate an accurate VM upward payment adjustment factor.

We propose to apply these policies for the CY 2017 VM and CY 2018 VM.

We request comments on these proposals.

The proposals described in this section would allow us to make predictable decisions as a result of informal reviews and unanticipated issues that may arise, providing greater certainty for groups and solo practitioners about impact of their results, as we foresee that several of the issues that impacted the CY 2016 VM, as described above, may continue to impact the CY 2017 and CY 2018 VM and/or new unanticipated issues may be identified. The proposals would also minimize the need to use PQRS data to recalculate the quality composite and prevent situations where we are making decisions on a case-by-case basis based on the TIN's PQRS reporting mechanism.

b. Application of the VM to Participant TINs in Shared Savings Program ACOs That Do Not Complete Quality Reporting

In the CY 2015 PFS final rule with comment period (79 FR 67946), for groups and solo practitioners, as identified by their TIN, that participate in a Shared Savings Program ACO, we finalized the same policy that is generally applicable to groups and solo practitioners that fail to satisfactorily report or participate under PQRS and thus fall in Category 2 and are subject to an automatic downward adjustment under the VM in CY 2017. We stated that, consistent with the application of the VM to other groups and solo practitioners that report under PQRS, if the ACO does not successfully report quality data as required by the Shared Savings Program under § 425.504, all groups and solo practitioners participating in the ACO will fall in Category 2 for the VM, and therefore, will be subject to a downward payment adjustment. We finalized this policy for the 2017 payment adjustment period for the VM. In the CY 2016 PFS proposed rule with comment period (80 FR 41899), we proposed to continue this policy in the CY 2018 payment adjustment period for all groups and solo practitioners subject to the VM that participate in a Shared Savings Program ACO and finalized our proposal in the CY 2016 PFS final rule (80 FR 71285).

As discussed in sections III.I. and III.L.1.e. of this proposed rule, we are proposing to remove the prohibition on EPs who are part of a group or solo practitioner that participates in a Shared Savings Program ACO, for purposes of PQRS reporting for the CY 2017 and CY 2018 payment adjustments, to report outside the ACO. As a result of this proposed policy, the EPs in groups and those who are solo practitioners would be allowed to report to the PQRS as a group (using one of the group registry, QCDR, or EHR reporting options) or individually (using the registry, QCDR, or EHR reporting option) outside of the ACO. This section addresses how we propose to use the PQRS data reported by EPs outside of the ACO for the CY 2018 VM when the ACO does not successfully report quality data on behalf of their EPs for purposes of PQRS as required by the Shared Savings Program under § 425.504.

For the CY 2018 payment adjustment period, if a Shared Savings Program ACO does not successfully report quality data on behalf of their EPs for purposes of PQRS as required by the Shared Savings Program under § 425.504, then we propose to use the data reported to the PQRS by the EPs (as a group (using one of the group registry, QCDR, or EHR reporting options) or as individuals (using the registry, QCDR, or EHR reporting option) under the participant TIN) outside of the ACO to determine whether the TIN would fall in Category 1 or Category 2 under the VM. We propose to apply the two-category approach finalized for the CY 2018 VM (80 FR 71280) based on participation in the PQRS by groups and solo practitioners to determine whether groups and solo practitioners that participate in a Shared Savings Program ACO, but report to the PQRS outside of the ACO, would fall in Category 1 or Category 2 under the VM. This proposed policy is consistent with our policy for groups and solo practitioners who are subject to the VM and do not participate in the Shared Savings Program, and we believe it would further encourage quality reporting by EPs in the event the ACO does not successfully report quality data as required by the Shared Savings Program under § 425.504. For example, if groups that participate in a Shared Savings Program ACO in 2016 report quality data to the PQRS outside of the ACO and meet the criteria to avoid PQRS payment adjustment for CY 2018 as a group using one of the group registry, QCDR, or EHR reporting options or have at least 50 percent of the group's EPs meet the criteria to avoid the PQRS payment adjustment for CY 2018 as individuals using the registry, QCDR, or EHR reporting option by reporting quality data to PQRS outside of the ACO, then they would be included in Category 1 for the CY 2018 VM. If solo practitioners that participate in a Shared Savings Program ACO in 2016 report quality data to the PQRS outside of the ACO and meet the criteria to avoid the PQRS payment adjustment for CY 2018 as individuals using the registry, QCDR, or EHR reporting option, then they would also be included in Category 1. Category 2 would include those groups and solo practitioners subject to the CY 2018 VM that participate in a Shared Savings Program ACO and do not fall within Category 1.

As finalized for the CY 2018 payment adjustment period (80 FR 71285), all groups and solo practitioners that participate in a Shared Savings Program ACO and fall in Category 2 will be subject to an automatic downward payment adjustment under the VM. For groups and solo practitioners that participate in a Shared Savings Program ACO that did not successfully report quality data as required by the Shared Savings Program under § 425.504 and are in Category 1 as a result of reporting quality data to the PQRS outside of the ACO, we propose to classify their quality composite for the VM for the CY 2018 payment adjustment period as "average quality." As finalized in the CY 2015 PFS final rule with comment period (79 FR 67943), the cost composite for groups and solo practitioners that participate in a Shared Savings Program ACO will be classified as "average cost." Because we would not have the ACO's quality data for these groups and solo practitioners, we believe it would be appropriate to use the quality data they reported to the PQRS outside the ACO to determine whether they avoided the PQRS payment adjustment and whether they would be in Category 1 or 2 for purposes of the VM, but not to calculate a quality composite using the quality-tiering methodology. As we stated previously, we continue to believe that it is appropriate to calculate a quality composite for groups and solo practitioners participating in the Shared Savings Program based on the ACO's quality data (79 FR 67944). This proposal is not intended to encourage groups and solo practitioners that participate in a Shared Savings Program ACO to report to the PQRS outside the ACO, but in the event the ACO does not successfully report quality data on behalf of their EPs for purposes of PQRS, to provide them with a safeguard that would allow them to avoid the PQRS payment adjustment and the automatic downward adjustment under the VM. We encourage groups and solo practitioners to continue to report through the ACO in order to promote clinical and financial integration within the ACO and for the Medicare beneficiaries they treat. For groups and solo practitioners that participate in a Shared Savings Program ACO that successfully reports quality data on behalf of their EPs for purposes of PQRS as required by the Shared Savings Program under § 425.504, we will calculate their VM for the CY 2018 payment adjustment period according to the policies established in the CY 2015 PFS final rule with comment period (79 FR 67941 to 67947 and 79 FR 67956 to 67957) and CY 2016 PFS final rule with comment period (80 FR 71283 to 71286 and 80 FR 71294). We solicit comment on these proposals. We are also proposing corresponding revisions to § 414.1210(b)(2).

As discussed in section III.H. of this proposed rule, to allow affected EPs that participate in an ACO to report separately for the CY 2017 PQRS payment adjustment, we are proposing a secondary PQRS reporting period for EPs that were in an ACO that did not successfully report quality data on behalf of the EPs in the group and those who are solo practitioners. Specifically, we are proposing that affected individual EPs or groups, who report under an ACO, may separately report outside the ACO either as individual EPs (using the registry, QCDR, or EHR reporting option) or using one of the group registry, QCDR, or EHR reporting options (note these EPs and groups would not need to register for one of these group reporting options, but rather mark the data as group data in their submission) during a secondary PQRS reporting period for the CY 2017 PQRS payment adjustment if they were a participant in an ACO that did not successfully report quality data on their behalf during the established reporting period for the CY 2017 PQRS payment adjustment. We are proposing the secondary PQRS reporting period for the CY 2017 PQRS payment adjustment would coincide with the reporting period for the CY 2018 PQRS payment adjustment (that is, January 1, 2016 through December 31, 2016).

This section addresses how we propose to use, for purposes of the CY 2017 VM, the PQRS data reported by the EPs in the group and those who are solo practitioners outside of the ACO using the secondary PQRS reporting period when the ACO did not successfully report quality data on behalf of their EPs for purposes of PQRS as required by the Shared Savings Program under § 425.504 for the CY 2017 PQRS payment adjustment. For the CY 2017 payment adjustment period, if a Shared Savings Program ACO did not successfully report quality data on behalf of their EPs for purposes of PQRS as required by the Shared Savings Program under § 425.504 for the CY 2017 PQRS payment adjustment, then we propose to use the data reported to the PQRS by the EPs (as a group using one of the group registry, QCDR, or EHR reporting options or as individuals using the registry, QCDR, or EHR reporting option) under the participant TIN) outside of the ACO during the secondary PQRS reporting period to determine whether the TIN would fall in Category 1 or Category 2 under the VM. We propose to apply the two-category approach finalized for the CY 2017 VM (79 FR 67938 to 67939 and as revised in 80 FR 71280 to 71281) based on participation in the PQRS by groups and solo practitioners to determine whether groups and solo practitioners that participate in a Shared Savings Program ACO, but report to the PQRS outside of the ACO, would fall in Category 1 or Category 2 under the VM. In section III.H. of this proposed rule, we are proposing to assess the individual EP or group's 2016 data submitted outside the ACO and during the secondary PQRS reporting period against the reporting requirements for the CY 2018 PQRS payment adjustment. Therefore, we propose that groups that meet the criteria to avoid PQRS payment adjustment for CY 2018 as a group practice participating in the PQRS GPRO (using one of the group registry, QCDR, or EHR reporting options) or have at least 50 percent of the group's EPs meet the criteria to avoid the PQRS payment adjustment for CY 2018 as individuals (using the registry, QCDR, or EHR reporting option), based on data submitted outside the ACO and during the secondary PQRS reporting period, would be included in Category 1 for the CY 2017 VM. We also propose that solo practitioners that meet the criteria to avoid the PQRS payment adjustment for CY 2018 as individuals using the registry, QCDR, or EHR reporting option, based on data submitted outside the ACO and during the secondary PQRS reporting period, would be included in Category 1 for the CY 2017 VM. Category 2 would include those groups and solo practitioners subject to the CY 2017 VM that participate in a Shared Savings Program ACO and do not fall within Category 1.

As finalized for the CY 2017 payment adjustment period (79 FR 67946), all groups and solo practitioners that participate in a Shared Savings Program ACO and fall in Category 2 will be subject to an automatic downward payment adjustment under the VM. For groups and solo practitioners that participate in a Shared Savings Program ACO that did not successfully report quality data as required by the Shared Savings Program under § 425.504 and are in Category 1 as a result of reporting quality data to the PQRS outside of the ACO using the secondary PQRS reporting period, we propose to classify their quality composite for the VM for the CY 2017 payment adjustment period as "average quality" for the same reasons described above for the CY 2018 payment adjustment period. As finalized in the CY 2015 PFS final rule with comment period (79 FR 67943), the cost composite for groups and solo practitioners that participate in a Shared Savings Program ACO will be classified as "average cost."

If EPs who are part of a group or a solo practitioner that participated in a Shared Savings Program ACO in 2015 that did not successfully report quality data on their behalf decide to use the secondary PQRS reporting period, it is important to note that such groups and solo practitioners should expect to be initially classified as Category 2 and receive an automatic downward adjustment under the VM for items and services furnished in CY 2017 until CMS is able to determine whether the group or solo practitioner met the criteria to avoid the PQRS payment adjustment as described above. First, we would need to process the data submitted for 2016. Second, we would need to determine whether or not the group or solo practitioner would be classified as Category 1 or Category 2 for the CY 2017 VM and notify the group or solo practitioner if there is a change in the VM status. Third, we would need to update the group or solo practitioner's status so that they will stop receiving an automatic downward adjustment under the VM for items and services furnished in CY 2017 and reprocess all claims that were previously paid. Since groups and solo practitioners taking advantage of this secondary reporting period for the 2017 VM will have missed the deadline for submitting an informal review request for the 2017 VM, we propose the informal review submission periods for these groups and solo practitioners would occur during the 60 days following the release of the QRURs for the 2018 VM.

We request comment on these proposals. We are also proposing corresponding revisions to § 414.1210(b)(2).

M. Physician Self-Referral Updates

1. Unit-Based Compensation in Arrangements for the Rental of Office Space or Equipment

a. The Physician Self-Referral Statute and Regulations

(1) Section 1877 of the Act

Section 6204 of the Omnibus Budget Reconciliation Act of 1989 (Pub. L. 101–239) (OBRA 1989), enacted on December 19, 1989, added section 1877 to the Act. Section 1877 of the Act, also known as the physician self-referral law: (1) Prohibits a physician from making referrals for certain designated health services (DHS) payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship (ownership or compensation), unless an exception applies; and (2) prohibits the entity from filing claims with Medicare (or billing another individual, entity, or third party payer) for those referred services. The statute establishes a number of specific exceptions, and grants the Secretary the authority to create regulatory exceptions for financial relationships that pose no risk of program or patient abuse. Additionally, the statute mandates refunding any amount collected under a bill for an item or service furnished under a prohibited referral. Finally, the statute imposes reporting requirements and provides for sanctions, including civil monetary penalty provisions. Section 1877 of the Act became effective on January 1, 1992.

Section 4207(e) of the Omnibus Budget Reconciliation Act of 1990 (Pub. L. 101–508) (OBRA 1990), enacted on November 5, 1990, amended certain provisions of section 1877 of the Act to clarify definitions and reporting requirements relating to physician ownership and referrals and to provide an additional exception to the prohibition. Several subsequent laws further changed section 1877 of the Act. Section 13562 of the Omnibus Budget Reconciliation Act of 1993 (Pub. L. 103–66) (OBRA 1993), enacted on August 10, 1993, expanded the referral prohibition to cover certain other "designated health services" in addition to clinical laboratory services, modified some of the existing statutory exceptions, and added new exceptions. Section 152 of the Social Security Act Amendments of 1994 (SSA 1994) (Pub. L. 103–432), enacted on October 31, 1994, amended the list of designated health services, changed the reporting requirements at section 1877(f) of the Act, and modified some of the effective dates established by OBRA 1993. Some provisions relating to referrals for clinical laboratory services were effective retroactively to January 1, 1992, while other provisions became effective on January 1, 1995.

(2) Regulatory History

(a) General Background

The following discussion provides a chronology of our more significant and comprehensive rulemakings; it is not an exhaustive list of all rulemakings related to the physician self-referral law.

Following the passage of section 1877 of the Act, we proposed rulemakings in 1992 (related only to referrals for clinical laboratory services) (57 FR 8588) (the 1992 proposed rule) and 1998 (addressing referrals for all DHS) (63 FR 1659) (the 1998 proposed rule). We finalized the proposals from the 1992 proposed rule in 1995 (60 FR 41914) (the 1995 final rule), and issued final rules following the 1998 proposed rule in three stages. The first final rulemaking (Phase I) was published in the January 4, 2001 **Federal Register** (66 FR 856) as a final rule with comment period. The second final rulemaking (Phase II) was published in the March 26, 2004 **Federal Register** (69 FR 16054) as an interim final rule with comment period. Due to a printing error, a portion of the Phase II preamble was omitted from the March 26, 2004 **Federal Register** publication. That portion of the preamble, which addressed reporting requirements and sanctions, was published on April 6, 2004 (69 FR 17933). The third final rulemaking (Phase III) was published in the September 5, 2007 **Federal Register** (72 FR 51012) as a final rule. In addition to Phase I, Phase II, and Phase III, we issued final regulations on August 19, 2008 in the "Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2009 Rates" final rule with comment period (73 FR 48434) (the FY 2009 IPPS final rule). That rulemaking made various revisions to the physician self-referral regulations, including provisions that prohibited certain per unit-of-service (often referred to as "per-click") and percentage-based compensation formulas for determining the rental charges for office space and equipment lease arrangements.

We issued additional final regulations after passage of the Affordable Care Act. In the CY 2011 PFS final rule with comment period (75 FR 73170), we codified a disclosure requirement established by the Affordable Care Act for the in-office ancillary services exception. We also issued regulations in the CY 2011 OPPS final rule with comment period (75 FR 71800), the CY

2012 OPPS final rule with comment period (76 FR 74122), and the CY 2015 OPPS final rule with comment period (79 FR 66770) that established or revised certain regulatory provisions concerning physician-owned hospitals to codify and interpret the Affordable Care Act's revisions to section 1877 of the Act. Finally, in the CY 2016 PFS final rule (80 FR 70886), we issued regulations to accommodate delivery and payment system reform, reduce burden, and to facilitate compliance. In that rulemaking, we established two new exceptions, clarified certain provisions of the physician self-referral law, updated regulations to reflect changes in terminology, and revised definitions related to physician-owned hospitals. One of the new exceptions, the exception for timeshare arrangements at § 411.357(y), includes a prohibition on certain per unit-of-service compensation formulas.

(b) Unit-Based Compensation

We have addressed the issue of unit-based compensation in several rulemakings. Sections 1877(e)(1)(A)(iv) and (B)(iv) of the Act provide that, for an arrangement for the rental of office space or equipment to satisfy the relevant exceptions to the physician self-referral law, the rental charges over the term of the lease must be set in advance, be consistent with fair market value, and not be determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties. Interpreting this "volume or value" standard in the 1998 proposed rule, we proposed that compensation could be based on units of service (for example, "per-use" equipment rentals) provided that the units of service did not include services provided to patients who were referred by the physician receiving the payment. For example, a physician who owned a lithotripter could rent it to a hospital on a per-procedure basis, except for lithotripsies for patients referred by the physician owner. Instead, payments for the use of the lithotripter for those patients would have to use a methodology that did not vary with referrals. (63 FR 1714; *see also* 66 FR 876). We further proposed that arrangements in which a physician rents equipment to an entity that furnishes a designated health service, such as a hospital that rents an MRI machine, with the physician receiving rental payments on a "per-use" or "per-click" basis (that is, a rental payment is generated each time the machine is used) do not prohibit the physician from otherwise referring to the entity, provided that these kinds of arrangements are typical and comply with the fair market value and other standards that are included under the rental exception. However, because a physician's compensation under this exception cannot reflect the volume or value of the physician's own referrals, we proposed that the rental payments may not reflect "per-use" or "per-click" payments for patients who are referred for the service by the physician lessor. (63 FR 1714)

After reviewing the public comments in response to the 1998 proposed rule, we finalized in Phase I significant revisions with respect to the scope of the volume or value standard. We revised our interpretation of the "volume or value" standard for purposes of section 1877 of the Act to permit, among other things, payments based on a unit of service, provided that the unit-based payment is fair market value and does not vary over time. (66 FR 876 through 879) Importantly, we permitted unit-based compensation formulas, even when the physician receiving the payment has generated the payment through a DHS referral. To reach this position, we reviewed the legislative history with respect to the statutory exceptions for the rental of office space and equipment and concluded that Congress intended that unit-of-service-based payments be protected under certain circumstances. (66 FR 878) Specifically, with respect to the exceptions for the rental of office space and equipment, the Conference Committee report, H. Rep. No. 213, 103rd Cong., 1st Sess. (1993) (the House Conference Report) states at page 814 that the conferees "intend[ed] that rental charges for [office] space and equipment leases may be based on daily, monthly, or other time-based rates, or rates based on units of service furnished, so long as the amount of the time-based or units of service rates does not fluctuate during the contract period based on the volume or value of referrals between the parties to the lease or arrangement." However, we stated our unequivocal belief that arrangements in which the lessor is compensated each time that the lessor refers a patient to the lessee for a service performed in the leased office space or using the leased equipment have an obvious potential for abuse and could incent overutilization (66 FR 878). We indicated that we would continue to monitor financial arrangements in the health care industry and would revisit particular regulatory decisions if we determine that there has been abuse or overutilization (66 FR 860).

In the CY 2008 PFS proposed rule (72 FR 38122), we stated that arrangements between a physician lessor and an entity lessee under which the physician lessor receives unit-of-service payments are inherently susceptible to abuse because the physician lessor has an incentive to profit from referring a higher volume of patients to the lessee. We proposed that space and equipment leases may not include per-click payments to a physician lessor for services rendered by an entity lessee to patients who are referred by a physician lessor to the entity (72 FR 38183). We also solicited comments on the question of whether we should prevent per-click payments in situations in which the physician is the lessee and a DHS entity is the lessor. The CY 2008 PFS proposed rule also included eight other significant proposed revisions to the physician self-referral regulations. Due to the large number of physician self-referral proposals, the significance of the provisions both individually and in concert with each other, and the volume of public comments received in response to the CY 2008 PFS proposed rule, we declined to finalize our proposals, including our proposal to prohibit certain per unit-of-service compensation formulas in arrangements for the rental of office space and equipment, in the CY 2008 PFS final rule (72 FR 66222).

After consideration of the public comments and our independent research, we finalized regulations prohibiting certain per-unit of service compensation formulas for determining office space and equipment rental charges in the FY 2009 IPPS final rule (73 FR 48434). Specifically, we revised § 411.357(a)(4) and (b)(4) to prohibit rental charges for the rental of office space or equipment that are determined using a formula based on per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee. In doing so, we relied on our authority in section 1877(e)(1)(A)(vi) and (B)(vi) of the Act, which permits the secretary to impose by regulation other requirements needed to protect against program or patient abuse. We also revised the exceptions at §§ 411.357(l) and (p) for fair market value compensation and indirect compensation arrangements, respectively, to include similar limitations on the formula for determining office space and equipment rental charges, as applicable. We did so using our authority at section 1877(b)(4) of the Act, as those exceptions were established using that authority. (*See* 73 FR 48713 through 48721) We determined it necessary to limit the type of per-click compensation formulas available for arrangements for the rental of office space and equipment because we believe that arrangements under which a lessor receives unit-of-service payments are inherently susceptible to abuse. Specifically, we believe that the lessor has an incentive to profit from referring a higher volume of patients to the lessee and from referring patients to the lessee that might otherwise go elsewhere for services.

b. Development of This Rulemaking

(1) Council for Urological Interests v. Burwell

On June 12, 2015, the D.C. Circuit (the Court) issued an opinion in *Council for Urological Interests* v. *Burwell,* 790 F.3d 212 (D.C. Cir. 2015), that addressed the prohibition on per-click rental charges for the lease of equipment found at § 411.357(b)(4)(ii)(B). In its ruling, the Court agreed with CMS that section 1877(e)(1)(B)(vi) of the Act provides the Secretary the authority to prohibit per-click leasing arrangements. The Court concluded that—

> The text of the statute does not unambiguously preclude the Secretary from using her authority to add a requirement that bans per-click leases. To the contrary, the statutory text of the exception clearly provides the Secretary with the discretion to impose any additional requirements that she deems necessary "to protect against program or patient abuse." (*Council for Urological Interests,* 790 F.3d at 219.)

The Court further concluded that the relevant language in the House Conference Report merely interpreted section 1877(e)(1)(B)(iv) of the Act, and thus did not preclude CMS from imposing additional requirements under section 1877(e)(1)(B)(vi) of the Act. It stated that the legislative history "simply indicates that, as written, the rental-charge clause [in section 1877(e)(1)(B)(iv) of the Act] does not preclude per-click leases" and stated further that "[n]othing in the legislative history suggests a limit on [the Secretary's] authority to prohibit per-click leases under section 1877(e)(1)(B)(vi) of the Act)." *Id.* at 222.

The Court also concluded, however, that CMS's discussion of the House Conference Report in the FY 2009 IPPS final rule contained an unreasonable interpretation of the conferees' statements concerning sections 1877(e)(1)(A)(iv) and (B)(iv) of the Act, and it remanded the case to the agency to permit a fuller consideration of the legislative history. This rulemaking addresses that decision.

(2) The FY 2009 IPPS Final Rule

As discussed above, in the FY 2009 IPPS final rule, we revised the exceptions for the rental of office space and equipment to include in each a requirement that the rental charges for the office space or equipment are not determined using a formula based on per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee. We explained that our decision to add this requirement was ultimately based on our authority under section 1877(e)(1)(B)(vi) of the Act to promulgate "other requirements" needed to protect against program or patient abuse. However, we also discussed certain legislative history contained in the House Conference Report addressing sections 1877(e)(1)(A)(iv) and 1877(e)(1)(B)(iv) of the Act, which establish requirements that rental charges over the term of a lease for office space or rental equipment be set in advance, be consistent with fair market value, and not be determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties. With respect to those statutory conditions, the language in the House Conference Report states that—

> The conferees intend that charges for space and equipment leases may be based on daily, monthly, or other time-based rates, or rates based on units of service furnished, so long as the amount of time-based or units of service rates does not fluctuate during the contract period based on the volume or value of referrals between the parties to the lease or arrangement. (H.R. Rep. No. 103–213, at 814 (1993).)

In the FY 2009 IPPS final rule, we noted that CMS had previously concluded that this language indicated that Congress intended to permit leases that included per-click payments, even for patients referred by the physician lessor (66 FR 940), but asserted that the language could also be interpreted as excluding from the office space and equipment lease exceptions those lease arrangements that include per-click payments for services provided to patients referred from one party to the other (73 FR 48716). Specifically, we stated that, where the total amount of rent (that is, the rental charges) over the term of the lease is directly affected by the number of patients referred by one party to the other, those rental charges can arguably be said to "take into account" or "fluctuate during the contract period based on" the volume or value of referrals between the parties. The Court found this revised interpretation to be an unreasonable reading of the language of the House Conference Report. The Court remanded § 411.357(b)(4)(ii)(B) to the Secretary for further proceedings consistent with its opinion, and directed that the Secretary should consider whether a ban on per-click equipment leases is consistent with the House Conference Report.

c. Re-proposal of Limitation on the Types of Per-Unit of Service Compensation Formulas for Determining Office Space and Equipment Rental Charges

In this proposed rule, we are re-proposing certain requirements for arrangements involving the rental of office space or equipment. Specifically, using the same language in existing §§ 411.357(a)(5)(ii)(B), (b)(4)(ii)(B), (l)(3)(ii), and (p)(1)(ii)(B), we are proposing to include at §§ 411.357(a)(5)(ii)(B), (b)(4)(ii)(B), (l)(3)(ii), and (p)(1)(ii)(B) a requirement that rental charges for the office space or equipment are not determined using a formula based on per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee. We are using the authority granted to the Secretary in sections 1877(e)(1)(A)(vi) and (B)(vi) of the Act to re-propose this requirement in the exceptions at § 411.357(a) and (b) for the rental of office space and equipment, respectively. We are using the authority granted to the Secretary in section 1877(b)(4) of the Act to re-propose this requirement in the exceptions at § 411.357(l) and (p) for fair market value compensation and indirect compensation arrangements, respectively.

We emphasize that we are not proposing an absolute prohibition on rental charges based on units of service furnished. In general, per-unit of service rental charges for the rental of office space or equipment are permissible. We are proposing to limit the general rule by prohibiting per-unit of service rental charges where the lessor generates the payment from the lessee through a referral to the lessee for a service to be provided in the rented office space or using the rented equipment. Thus, per-unit of service rental charges for the rental of office space or equipment would be permissible, but only in those instances where the referral for the service to be provided in the rented office space or using the rented equipment did not come from the lessor.

(1) Authority

In accordance with the Court's opinion in *Council for Urological*

Interests, we set forth below the Secretary's authority to include in the exceptions applicable to office space and equipment leases a requirement that rental charges are not determined using a formula based on per-unit of service rental charges that reflect services provided to patients referred by the lessor to the lessee. Our determination follows the Court's reasoning, which we excerpt below, in rejecting the Council for Urological Interests' assertion that the Secretary lacks the authority to impose a ban on "per-click" equipment—and by correlation—office space leases. We also describe why limiting the types of per-click rental charges that would not violate the physician self-referral law's referral and claims submission prohibitions is consistent with the language of the House Conference Report.

As the Court stated, the physician self-referral law gives the Secretary power to add requirements as needed to protect against program or patient abuse, even if Congress did not anticipate such abuses at the time of enactment of the statute. Specifically, although Congress may not have originally included a ban on per-click rental charges in office space and equipment lease arrangements, it "empowered the Secretary to make her own assessment of the needs of the Medicare program and regulate accordingly." (*Council for Urological Interests,* 790 F.3d at 220.) The statute explicitly permits the Secretary to impose additional conditions on arrangements for the rental of office space or equipment, and nowhere expressly states that per-click rates must always be permitted. Thus, as the Court confirmed, the Secretary's regulation "can properly be classified as an 'other' requirement expressly permitted by sections 1877(e)(1)(A)(vi) and (B)(vi) of the Act." (*Id.*)

The Secretary's authority to impose requirements regarding the type of compensation formulas upon which office space and equipment rental charges may be based is not constrained by the House Conference Report. As discussed elsewhere in this proposed rule, we acknowledge that the language in the House Conference Report states Congress' intent at the time of enactment of the physician self-referral law that sections 1877(e)(1)(A)(iv) and (B)(iv) of the Act not be interpreted as prohibiting charges for the rental of office space or equipment that are based on units of service furnished. We do not purport here to interpret this language as implying anything other than the conferees' understanding—at the time of enactment of the statute—that the statute as written did not prohibit rental charges based on units of service rates. But Congress also gave the Secretary the authority in sections 1877(e)(1)(A)(vi) and (B)(vi) of the Act to impose by regulation other requirements as needed to protect against program or patient abuse, which could only happen *after* the enactment of the statute. Nowhere in the House Conference Report did Congress express an intent to limit the authority granted to the Secretary in sections 1877(e)(1)(A)(vi) and (B)(vi) of the Act (as enacted). In fact, the House Conference Report was completely silent regarding sections 1877(e)(1)(A)(vi) and (B)(vi) of the Act, leaving the express words of the statute to speak for themselves. As the Court noted—

> The conference report . . . states only that rental charges "may" be based on units of service. The language is not obligatory. Instead, it simply indicates that, as written, the rental-charge clause [(section 1877(e)(1)(B)(iv) of the Act)] does not preclude per-click leases. But, as we have already explained, there is more to the statute than this clause, and to qualify for the exception, a rental agreement must comply with all six clauses, not merely the rental-charge clause alone. The final clause [(section 1877(e)(1)(B)(vi) of the Act)] gives the Secretary the authority to add further requirements. Nothing in the legislative history suggests a limit on this authority. We conclude that the statute does not unambiguously forbid the Secretary from banning per-click leases as she evaluates the needs of the Medicare system and its patients. (790 F.3d at 221–22 (*footnote omitted*))

Moreover, as the Court further noted, a statement that unit of service-based rental charges are not precluded by sections 1877(e)(1)(A)(iv) and (B)(iv) of the Act as they are written is not equivalent to a statement that the Secretary must continue to permit such charges as she reevaluates, in light of experience, the operation of the statute and the need to protect the Medicare program and its beneficiaries against abuse. (*Id.* at 222 n.7; *see also id.* at 222 n.6 ("Congress has expressly delegated to the Secretary the authority to promulgate additional requirements, as she has done here, and the legislative history does not clearly impose a constraint on that power.")).

The Secretary has broad authority under sections 1877(e)(1)(A)(vi) and (B)(vi) of the Act to impose conditions on arrangements for the rental of office space or equipment in order to protect against program or patient abuse. That authority is not limited by the express words of the statute as it is in other provisions of section 1877 of the Act. In agreement, the Court in *Council for Urological Interests* explained—

> . . . Congress knew how to limit the Secretary's authority to impose additional requirements to the various exceptions [to the physician self-referral law]. In [section 1877(e)(2) of the Act], Congress excludes bona fide employment relationships from the definition of compensation arrangements. This provision states that the employment relationship must comply with various requirements, including that the pay not be determined "in a manner that takes into account (directly or indirectly) the volume or value of any referrals by the referring physician." This employment exception also allows the Secretary to impose "other requirements," just as the equipment rental exception. But the statute then goes on to say that the listed requirements "shall not prohibit the payment of remuneration in the form of a productivity bonus based on services performed personally by the physician." This language shows that Congress knew how to cabin the Secretary's authority to impose "other" requirements and that it knew how to further clarify what it meant by compensation that does not take into account the volume of business generated between parties. That Congress employed neither of these tools with reference to the [exception for the rental of office space or equipment] again supports reading the statute as giving the Secretary broad discretion as she regulates in this area. (790 F.3d at 221 (citations omitted))

The Secretary's authority to limit the use of per-unit of service rental charges in arrangements for the rental of office space or equipment is particularly clear when the exceptions for the rental of office space and equipment are compared to other provisions in section 1877 of the Act. According to the Court in *Council for Urological Interests—*

> [T]he statute elsewhere expressly permits charging per-click fees in other contexts, showing that Congress knew how to authorize such payment terms when it wanted to. In [section 1877(e)(7)(A) of the Act], Congress created an exception to the [physician self-referral law] that allows the continuation of certain group practice arrangements with a hospital. . . . The provision states that "[a]n arrangement between a hospital and a group under which designated health services are provided by the group but are billed by the hospital" is excepted from the ban on referrals if, among other things, "the compensation paid over the term of the agreement is consistent with fair market value and the compensation *per unit of services* is fixed in advance and is not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties." Comparing this provision to the [exceptions for the rental of office space and equipment] shows that Congress knew how to permit per-click payments explicitly, suggesting that the omission in this particular context was deliberate. . . . In other words, Congress's decision not to include similar language in the [exceptions for the rental of

> office space and equipment] supports our conclusion that the statute is silent regarding the permissibility of per-click leases for equipment rentals. (790 F.3d at 220–21 (citations omitted))

In summary, as we stated in the FY 2009 IPPS final rule (73 FR 48716), the physician self-referral statute responds to the context of the times in which it was enacted (by addressing known risks of overutilization and, in particular, by creating exceptions for common business arrangements), and also incorporates sufficient flexibility to adapt to changing circumstances and developments in the health care industry. For example, in section 1877(b)(4) of the Act, Congress authorized the Secretary to protect additional beneficial arrangements by promulgating new regulatory exceptions. In addition, Congress included the means to address evolving fraud risks by inserting into many of the exceptions—and notably, for our purposes, in the lease exceptions—specific authority for the Secretary to add conditions as needed to protect against abuse. This design reflects a recognition that a fraud and abuse law with sweeping coverage over most of the health care industry could not achieve its purpose over the long term if it were frozen in time. In short, the statute evidences Congress' foresight in anticipating that the nature of fraud and abuse—and of beneficial industry arrangements—might change over time. (73 FR 48716 (citations omitted))

As we did in 2007 when we first proposed to impose additional requirements for rental charges in arrangements for the rental of office space and equipment, and in 2008 when we finalized regulations incorporating such additional requirements, we are relying in this proposal on the Secretary's clear authority in sections 1877(e)(1)(A)(vi) and (B)(vi) of the Act to impose such other requirements needed to protect against program or patient abuse. With respect to our proposal to include the same requirements at § 411.357(l) and (p), we have determined that the proposed revisions to § 411.357(l) and (p) are necessary to meet the standard set forth in section 1877(b)(4) of the Act, which authorizes the Secretary to establish exceptions to the statute's referral and billing prohibitions only where the excepted financial relationships do not pose a risk of program or patient abuse.

(2) Rationale for Proposal

As we discussed in prior rulemakings, including the 1998 proposed rule, a number of studies prior to the enactment of the physician self-referral law found that physicians who had financial relationships with entities to which they referred patients ordered more services than physicians without such financial relationships (63 FR 1661). Studies conducted since that time, including recent studies by GAO, indicate that financial self-interest continues to affect physicians' medical decision making.

In the FY 2009 IPPS final rule, we discussed in detail our rationale for finalizing the limitation on per-unit of service rental charges in arrangements for the rental of office space or equipment. We noted primary concerns regarding the potential for overutilization, patient steering and other anti-competitive effects, and reduction in quality of care and patient outcomes, as well as concerns regarding the potential for increased costs to the Medicare program. For the reasons set forth in the FY 2009 IPPS final rule, some of which are restated below, we believe that, in order to protect against program or patient abuse, it is necessary to impose additional requirements on arrangements for the rental of office space or equipment. Specifically, we believe that it is necessary to prohibit rental charges that are determined using a formula based on per-unit of service rental charges to the extent that such charges reflect services provided to patients referred by the lessor to the lessee of the office space or equipment.

Commenters responding to our proposal in the CY 2008 PFS proposed rule to impose additional requirements for office space and equipment lease arrangements provided compelling information regarding potential program or patient abuse. We were persuaded in 2008 to finalize requirements limiting per-unit of service rental charges in the exceptions applicable to the rental of office space or equipment, and believe today that these requirements continue to be necessary, due to our concerns that "per-click" lease arrangements in which the lessor makes referrals to the lessee that generate payments to the lessor—

- Creates an incentive for overutilization of imaging services (as described by MedPAC in its comments to our proposal in the CY 2008 PFS proposed rule), as well as other services, including therapeutic services;
- Creates an incentive for physicians to narrow their choice of treatment options to those for which they will realize a profit, even where the best course of action may be no treatment;
- Influence physicians to refer to the lessee instead of referring to another entity that utilizes the same or different (and perhaps more efficacious) technology to treat the patient's condition;
- Result in physicians steering patients to equipment they own, even if it means having the patient travel to a non-convenient site for services using the leased equipment; and
- Increase costs to the Medicare program when referring physicians pressure hospitals to use their leasing company despite not being the low cost provider.

Most recently, in the CY 2016 PFS final rule, we expressed our continued concern that, when physicians have a financial incentive to refer a patient to a particular entity, this incentive can affect utilization, patient choice, and competition. Physicians can overutilize by ordering items and services for patients that, absent a profit motive, they would not have ordered. A patient's choice is diminished when physicians steer patients to less convenient, lower quality, or more expensive providers of health care, just because the physicians are sharing profits with, or receiving remuneration from, the providers. And lastly, where referrals are controlled by those sharing profits or receiving remuneration, the medical marketplace suffers if new competitors cannot win business with superior quality, service, or price (80 FR 41926). In that rule, in establishing the exception at § 411.357(y) for timeshare arrangements, we determined it necessary to exclude from the exception any timeshare arrangements that incorporate compensation formulas based on: (1) A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services provided while using the timeshare; or (2) per-unit of service fees, to the extent that such fees reflect services provided to patients referred by the party granting permission to use the timeshare to the party to which the permission is granted. We explained our belief that timeshare arrangements based on percentage compensation or per-unit of service compensation formulas present a risk of program or patient abuse because they may incentivize overutilization and patient steering. We noted, by way of example, that a per-patient compensation formula could incent the timeshare grantor to refer patients (potentially for unnecessary consultations or services) to the party using the timeshare because the grantor will receive a payment each time the premises, equipment, personnel, items, supplies, or services are used. (80 FR 71331 through 71332) Similarly, we believe that arrangements utilizing rental charges for the rental of office space or equipment that are determined using a formula that rewards the lessor for each service the lessor refers to the lessee are susceptible to this and other abuse.

Finally, we note that we are not alone in our concern regarding overutilization and steering of beneficiaries resulting from arrangements in which a physician's referral may provide future remuneration back to the physician. In two notable advisory opinions, OIG expressed its concern with per-unit of service compensation arrangements. Specifically, in Advisory Opinion 03–08, OIG stated that " '[p]er patient,' 'per click,' 'per order,' and similar payment arrangements with parties in a position, directly or indirectly, to refer or recommend an item or service payable by a federal health care program are disfavored under the anti-kickback statute. The principal concern is that such arrangements promote overutilization . . . ." In Advisory Opinion 10–23, OIG noted that the arrangement that was the subject of the opinion "involves a 'per-click' fee structure, which is inherently reflective of the volume or value of services ordered and provided . . . ."

2. Technical Correction: Advisory Opinions Relating to Physician Referrals, Procedure for Submitting a Request

We are proposing to revise § 411.372(a) by making a minor technical correction to change the instructions for submitting a request for an advisory opinion relating to physician referrals. The current language in this subsection directs a requesting party to submit its request to a physical address that is out of date. In an effort to expedite the receipt and processing of these requests, and to account for any future changes, we are proposing to revise paragraph (a) to state a party or parties must submit a request for an advisory opinion to CMS according to the instructions specified on the CMS Web site.

We note that, at the time of this rulemaking, the correct address for such advisory opinion requests is: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Office of Financial Management, Division of Premium Billing and Collections, Mail Stop C3–09–27, Attention: Advisory Opinions, 7500 Security Boulevard, Baltimore, MD 21244–1850. However, we note that this address is subject to change, per this technical correction, and that parties seeking to submit a request for an advisory opinion relating to physician referrals will need to refer to the instructions on the CMS Web site.

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), we are required to publish a 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval.

To fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our burden estimates.
- The quality, utility, and clarity of the information to be collected.
- Our effort to minimize the information collection burden on the affected public, including the use of automated collection techniques.

We are soliciting public comment on each of the required issues under section 3506(c)(2)(A) of the PRA for the following information collection requirements (ICRs).

A. Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2015 National Occupational Employment and Wage Estimates for all salary estimates (*http://www.bls.gov/oes/current/oes_nat.htm*). In this regard, Table 39 presents the mean hourly wage, the cost of fringe benefits (calculated at 100 percent of salary), and the adjusted hourly wage.

TABLE 39—NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

Occupation title	Occupation code	Mean hourly wage ($/hr)	Fringe benefit ($/hr)	Adjusted hourly wage ($/hr)
Compliance Officer	13–1041	33.26	33.26	66.52
Epidemiologist	19–1040	36.97	36.97	73.94
Medical Scientist	19–1042	45.06	45.06	90.12
Medical Secretary	43–6013	16.50	16.50	33.00
Non-Physician Practitioner (Health Diagnosing and Treating Practitioners)	29–1000	46.65	46.65	93.90
Office and Administrative Support Operations	43–0000	17.47	17.47	34.94
Physicians and Surgeons	29–1060	97.33	97.33	194.66
Physicians and Surgeons, All Other	29–1069	95.05	95.05	190.10
Statistician	15–2041	40.60	40.60	81.20

As indicated, we are adjusting our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Nonetheless, there is no practical alternative and we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

B. Proposed Information Collection Requirements (ICRs) and Burden Estimates

1. ICRs Regarding the Physician Quality Reporting System (PQRS) (§ 414.90)

For individual EPs or group practices, who choose to separately report quality measures during the proposed secondary PQRS reporting period for the 2017 PQRS payment adjustment, who bill under the TIN of an ACO participant if the ACO failed to report on behalf of such EPs or group practices during the previously established reporting period for the 2017 PQRS payment adjustment, we do not believe the individual EP or group practice incurs any additional burden. The associated reporting burden which is currently approved by OMB under control number 0938–1059 (CMS–10276) explains that the PQRS annual burden estimate was calculated separately for (1) individual eligible professionals and group practices using the claims (for eligible professionals only), (2) qualified registry and QCDR,

(3) EHR-based reporting mechanisms, and (4) group practices using the GPRO. We estimated that ALL 1.25 million eligible professionals will participate in the PQRS in 2016 for purposes of meeting the criteria for satisfactory reporting (or, in lieu of satisfactory reporting, satisfactory participation in a QCDR) for the 2018 PQRS payment adjustment. This is a high estimate according to the 2014 PQRS Reporting Experience and Trends Report which found approximately 822,000 EPs participated in PQRS in 2014. Therefore, the additional EPs who choose to report separately from the ACOs have already been accounted for in the PQRS burden. We estimate there were approximately 1,947 EPs that are part of the 218 participant TINs that are under the 8 ACOs that failed to successfully report their 2015 quality data. There is no change in the reporting mechanisms or reporting criteria for PQRS. It is important to note that if the ACO fails to report on behalf of an EP or group practice and the EP or group practice does not utilize this secondary reporting period they may be subject to a downward adjustment.

2. ICRs Regarding Appropriate Use Criteria for Advanced Diagnostic Imaging Services (§ 414.94)

Consistent with section 1834(q) of the Act (as amended by section 218(b) of the PAMA), we have proposed specific requirements for clinical decision support mechanisms (CDSMs) that can be qualified CDSMs under § 414.94 of our regulations as part of the Medicare appropriate use criteria (AUC) program. CDSMs that believe they meet the requirements to be qualified CDSMs (for the purpose of this section) may apply to CMS to be specified as a qualified CDSM.

Applications must be submitted electronically and demonstrate how the CDSM meets the requirements under § 414.94(g)(1). Specifically, applications must demonstrate how the CDSM: (1) Makes available specified applicable AUC and related documentation supporting the appropriateness of the applicable imaging service ordered; (2) identifies the appropriate use criterion consulted in the event the CDSM makes available more than one criterion relevant to a consultation for a patient's specific clinical scenario; (3) makes available, at a minimum, specified applicable AUC that reasonably encompass the entire clinical scope of all priority clinical areas identified in § 414.94(e)(5); (4) has the technical capability to incorporate specified applicable AUC from more than one qualified PLE; (5) determines the extent to which an applicable imaging service is consistent with a specified applicable appropriate use criterion consulted for a patient's specific clinical scenario, or a determination of "not applicable" when the mechanism does not contain a criterion applicable to that patient's specific clinical scenario; (6) generates and provides a certification or documentation each time an ordering professional consults a qualified CDSM that includes a unique consultation identifier to the ordering professional that documents which qualified CDSM was consulted, the name and national provider identifier (NPI) of the ordering professional that consulted the CDSM, and whether the service ordered would adhere to specified applicable AUC or whether specified applicable AUC was not applicable to the service ordered; (7) updates AUC content at least every 12 months to reflect revisions or updates made by qualified PLEs to their AUC sets or an individual appropriate use criterion; (8) has a protocol to expeditiously remove AUC determined by the qualified PLE to be potentially dangerous to patients and/or harmful if followed; (9) makes available for consultation specified applicable AUC that reasonably encompass the entire clinical scope of any new priority clinical area within 12 months of the priority clinical area being finalized by CMS; (10) meets privacy and security standards under applicable provisions of law; (11) provides the ordering professional aggregate feedback regarding their consultation with specified applicable AUC in the form of an electronic report on an annual basis; (12) maintains electronic storage of clinical, administrative, and demographic information of each unique consultation for a minimum of 6 years; and (13) complies with modification(s) to any requirements under § 414.94(g)(1) made through rulemaking within 12 months of the effective date of the modification.

To be specified as a qualified CDSM by CMS, mechanism developers must document adherence to the requirements in their application for CMS review and use the application process identified in § 414.94(g)(2) which includes: (1) Applications submitted by CDSMs documenting adherence to each requirement outlined in § 414.94(g)(1) must be received annually by January 1; (2) all approved qualified CDSMs in each year will be included on the list of qualified CDSMs posted to the CMS Web site by June 30 of that year; (3) approved CDSMs are qualified for a period of 5 years; and (4) all qualified CDSMs must re-apply every 5 years and applications must be received by CMS by January 1 of the 5th year after the developer's most recent approval date. If a qualified CDSM is found to be non-adherent to the requirements identified above, CMS may terminate its qualified status or may consider this information during re-qualification.

The one-time burden associated with the requirements under § 414.94(g)(2) is the time and effort it would take each of the approximately 30 CDSM developers (as estimated by CMS, the Office of the National Coordinator (ONC), and the Agency for Healthcare Research and Quality (AHRQ)) that have interests in incorporating AUC consultation into their mechanisms' functionality to compile, review and submit documentation demonstrating adherence to the proposed CDSM requirements. We anticipate 30 respondents based on the number of existing CDSMs that have expressed an interest in incorporating AUC for advanced diagnostic imaging, as well as our estimation of the number of CDSM developers that may be interested in incorporating AUC for advanced diagnostic imaging in the future as their mechanisms develop and evolve. Each respondent will voluntarily compile, review and submit documentation that demonstrates their adherence to the proposed CDSM requirements listed above.

We estimate it would take 10 hours at $68.18/hr for a business operations specialist to compile, prepare and submit the required information, 2.5 hours at $86.72/hr for a computer system analyst to review and approve the submission, 2.5 hours at $135.58/hr for a computer and information systems manager to review and approve the submission, and 5 hours at $131.02/hr for a lawyer to review and approve the submission. In this regard, we estimate 20 hours per submission at a cost of $1,892.65. In aggregate, we estimate 600 hours (20 hr × 30 submissions) at $56,779.50 ($1,892.65 × 30 submissions).

After the anticipated initial 30 respondents, we expect less than 10 applicants to apply to become qualified CDSMs annually. Since we estimate fewer than 10 respondents, the information collection requirements and burden are exempt (5 CFR 1320.2(c)) from the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq).

Given that qualified CDSMs must re-apply every 5 years, in years 6–10, we expect the initial 30 entities will re-apply. The ongoing burden for re-applying is expected to be half the burden of the initial application process. The CDSM developers will be able to make modifications to their original application which should result in a burden of 5 hr at $68.18/hr for a business operations specialist to compile, prepare and submit the required information, 1.25 hr at $86.72/hr for a computer system analyst to review and approve the submission, 1.25 hr at $135.58/hr for a computer and information systems manager to review and approve the submission, and 2.5 hr at $131.02/hr for a lawyer to review and approve the submission. Annually, we estimate 10 hr per submission at a cost of $946.33 per CDSM developer. In aggregate, we estimate 300 hr (10 hr × 30 submissions) at $28,389.90 ($946.33 × 30 submissions).

As regulatory requirements become more complex, we will look to innovative technologies that minimize the burden on an organizations' budget and manpower. To this end, the proposed CDSM functionality requirements identified in § 414.94(g)(1) will help practitioners meet the requirements of the AUC program. While the CDSM application process proposed in § 414.94(g)(2) is a new burden under this program, the CDSM functionality requirements proposed in § 414.94(g)(1) do not add burden as they are functions of the CDSM. These mechanisms function consistently with their voluntary and individualized design so the proposed requirements in § 414.94(g)(1) are either part of a mechanism's functionality or not. If CDSM developers wish to become qualified under this program, they may choose to develop the functionality of their mechanisms consistent with these requirements to be qualified, but all CDSMs are not required to participate in this program. For example, a CDSM that does not incorporate AUC for any advanced diagnostic imaging services would likely choose not to seek to become qualified under this Medicare AUC program. As such, only CDSMs that wish to participate in the Medicare AUC for advanced diagnostic imaging services program are required to apply for qualification and, in choosing to seek qualification, CDSM developers would also choose to incorporate the proposed requirements into their mechanism's functionality.

The proposed requirements and burden will be submitted to OMB under control number 0938—New (CMS–10624).

3. ICRs Regarding the Enrollment of MA Providers, Suppliers, and First-Tier, Downstream, and Related Entities (FDRs) (§ 422.222)

There are approximately 1.9 million providers and suppliers nationwide that are enrolled in Medicare. Through our analysis of currently available encounter data provided by MA organizations, we have found that some providers and suppliers that furnish items or services to MA organization enrollees are not enrolled in Medicare in an approved status. Based on preliminary data, we estimate that 64,000 MA providers and suppliers would have to enroll in Medicare pursuant to proposed § 422.222 in order to treat enrollees.

About half of the approximately 64,000 unenrolled providers and suppliers, or 32,000, are individuals and the other half are organizations. We do not have data at this point to confirm the number of unenrolled individuals who are physicians as opposed to non-physician practitioners. For purposes of fulfilling the requirements of the PRA, we will project that one-half (16,000) are physicians and the other half (16,000) are practitioners.

Consistent with our prior time (per respondent) estimates, we project that it would take 3 hours at $194.66/hr for a physician and $93.30/hr for a non-physician practitioner to complete their individual enrollments. For organizations (office and administrative support personnel), we estimate it would take 6 hours at $34.94/hr, since organizations typically submit more data than individuals. For physicians, we estimate 48,000 hours (16,000 applicants × 3 hours) at a cost of $9,343,680 (48,000 hr × $194.66/hr). For non-physician practitioners, we estimate 48,000 hours (16,000 applicants × 3 hours) at a cost of $4,478,400 (48,000 hr × $93.30/hr). For organizations, we estimate 192,000 hours (32,000 applicants × 6 hours) at a cost of $6,708,480 (192,000 hr × $34.94). In aggregate, we estimate 288,000 hours at $20,530,560.

When projected annually over OMB's maximum 3-year approval period, we estimate 96,000 hours at a cost of $6,843,520.

For physicians and non-physician practitioners, the proposed requirements and annualized burden (32,000 hours) will be submitted to OMB under control number 0938–0685 (Form CMS–855I) because physicians and non-physician practitioners enroll via the Form CMS–855I. For organizations, the proposed requirements and annualized burden (64,000 hours) will be submitted to OMB under control number 0938–0685 (21,333.3 hours for Form CMS–855A and 21,333.3 hours for Form CMS–855B) and control number 0938–1056 (21,333.3 hours for Form CMS–855S). The specific form to be completed would depend upon the provider or supplier type at issue. For instance, and consistent with current enrollment policy, certified providers and certain certified suppliers would complete the Form CMS–855A; group practices, ambulance suppliers, and certain other supplier types would complete the Form CMS–855B; suppliers of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) would complete the Form CMS–855S.

Please note that breakout of the organization burden (dividing 64,000 hours by 3 forms) is an estimate. Logistically this is necessary for the purposes of submitting burden for approval. We have no way of estimating the number of providers/suppliers that will complete the individual forms. We welcome comment to help us derive a more reliable breakout.

4. ICRs Regarding Application Requirements (§ 422.501) and Termination of Contract by CMS (§ 422.510)

Changes proposed for §§ 422.501 and 422.510 involve only CMS contract changes and will not result in any external charges or operational costs to MA organizations. Many MA organizations already require Medicare enrollment for all their network providers and suppliers. So there will be no additional costs to most MA and MA- PD plans. The only tangible costs would be to those providers or suppliers that are not enrolled and those costs are estimated above.

5. ICRs Regarding the Release of Medicare Advantage Bid Pricing Data (§ 422.272) and the Release of Part C and Part D Medical Loss Ratio (MLR) Data (§§ 422.2490 and 423.2490)

Section 422.272 proposes an annual public release of MA bid pricing data (with specified exceptions from release), which would occur after the first Monday in October and would contain MA bid pricing data that was approved by CMS for a contract year at least five years prior to the upcoming calendar year. Under Part C, MA organizations (MAOs) are required to submit bid data to CMS each year for MA plans they wish to offer in the upcoming contract year (calendar year), under current authority at § 422.254.

Proposed §§ 422.2490 (for Part C) and 423.2490 (for Part D) would also provide for the public release of Part C and Part

D MLR data for each contract year, which would occur no sooner than 18 months after the end of the contract year for which the MLR Report was submitted. Starting with contract year 2014, if an MAO or Part D sponsor fails to spend at least 85 percent of the revenue received under an MA or Part D contract on incurred claims and quality improving activities, the MAO or Part D sponsor must remit to the Secretary the product of: (1) The contract's total revenue; and (2) the difference between 85 percent and the contract's MLR. For each contract year, each MAO and Part D sponsor must submit an MLR Report to CMS which includes the data needed by the MAO or Part D sponsor to calculate and verify the MLR and remittance amount, if any, for each contract. The proposed rule would allow us to release the Part C and Part D MLR data contained in the MLR Reports that we receive from MAOs and Part D sponsors, with specified exceptions to release.

The proposed provisions on release of MA bid pricing data and release of Part C and Part D MLR data do not change any of the existing requirements regarding submission of bid data and MLR data by MAOs or Part D sponsors. Nor does this rule propose any new or revised reporting, recordkeeping, or third-party disclosure requirements. Although the proposed provisions have no impact on respondent requirements or burden, the changes will be submitted to OMB for approval under control number 0938–0944 (CMS–10142) for MA bid pricing data and 0938–1232 (CMS–10476) for Part C and Part D MLR data.

6. ICRs Regarding the Medicare Shared Savings Program (Part 425)

Section 1899(e) of the Act provides that chapter 35 of title 44 of the U.S. Code, which includes such provisions as the PRA, shall not apply to the Shared Savings Program.

C. Summary of Annual Burden Estimates for Proposed Requirements

TABLE 40—PROPOSED ANNUAL RECORDKEEPING AND REPORTING REQUIREMENTS

Regulation section(s) under title 42 of the CFR	OMB Control No.	Respondents	Total responses	Burden per response (hours)	Total annual burden (hours)	Labor cost of reporting ($)	Total cost ($) *
§ 414.94(g)(2)	0938—New	30	30	20	600	varies	56,780
§ 414.94(g)(2) (reapply)	0938—New		30	10	300	varies	28,390
§ 422.222 (physicians and non-physician practitioners).	0938–0685	32,000	10,666.6 (32,000 responses annualized over 3 years).	3	32,000	varies	4,607,360
§ 422.222 (organizations)	0938–0685	32,000	7,111.1 for two CMS–855 forms (21,333.3 responses annualized over 3 years).	6	42,666.6	34.94	1,490,771
§ 422.222 (organizations)	0938–1056		3,555.6 for one CMS–855 form.	6	21,333.3	34.94	745,386
Total		64,030	64,060		96,900	varies	6,928,687

* This rule does not propose any non-labor costs.

D. Associated Information Collections Not Specified in Regulatory Text

In this proposed rule, we make reference to proposed associated information collection requirements that were not discussed in the regulation text contained in this proposed rule. The following is a discussion of those requirements.

1. Global Surgical Services

Section II.D.2. of this proposed rule details our plans for a proposed claims based reporting program for global surgical services. Specifically, that section describes our proposal for claims-based data collection that would be applicable to 10- and 90-day global services furnished on or after January 1, 2017, including who would be required to report, what they would be required to report, and how reports would be submitted. As currently proposed, this data collection would be subject to the PRA. As stated in section 220 of the Protecting Access to Medicare Act (PAMA) of 2014 (Pub. L. 113–93), Chapter 35 of title 44, United States Code, shall not apply to information collected or obtained under this paragraph. Specifically, information collected to ensure the accurate valuation of services under the Physician Fee Schedule which includes but is not limited to surveys of physicians, other suppliers, providers of services, manufacturers, and vendors; surgical logs, billing systems, or other practice or facility records; electronic health records; and, any other mechanism deemed appropriate by the Secretary.

2. Survey of Practitioners

As discussed earlier in section II.D.6. e.(1)–(2) of this document, we are proposing to conduct a survey of providers to help us explore options and collect data with respect to assessing and revaluing the global surgery services. If we finalize this proposal, the associated information collection request will be exempt from the PRA. As stated in stated in section 220 of PAMA of 2014, Chapter 35 of title 44, United States Code, shall not apply to information collected to ensure the accurate valuation of services under the Physician Fee Schedule. Consequently, the information collection requirements associated with this proposed survey need not be reviewed by the Office of Management and Budget.

3. Data Collection for Accountable Care Organizations

In section II.D6.e.(3) of this document, we propose to conduct a survey of ACOs on a number of issues surrounding pre- and post-operative surgical services. Once developed and implemented, the survey would be exempt from the PRA. As stated in section 3022 of the Affordable Care Act, Chapter 35 of title 44, United States Code, shall not apply to the Medicare Shared Savings Program. Similarly, as stated in stated in section 220 of PAMA of 2014, Chapter 35 of title 44, United States Code, shall not apply to information collected to ensure the accurate valuation of services under the Physician Fee Schedule. Consequently, the information collection requirements associated with this proposed survey need not be reviewed by the Office of Management and Budget.

E. Submission of PRA-Related Comments

We have submitted a copy of this proposed rule to OMB for its review of the rule's information collection and recordkeeping requirements. These requirements are not effective until they have been approved by the OMB.

To obtain copies of the supporting statement and any related forms for the proposed collections discussed above, please visit CMS' Web site at *www.cms.hhs.gov/PaperworkReductionActof1995*, or call the Reports Clearance Office at 410–786–1326.

We invite public comments on these potential information collection requirements. If you wish to comment, please submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule and identify the rule (CMS–1654–P) the ICR's CFR citation, CMS ID number, and OMB control number.

ICR-related comments are due September 13, 2016.

V. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

VI. Regulatory Impact Analysis

A. Statement of Need

This proposed rule is necessary to make payment and policy changes under the Medicare PFS and to make required statutory changes under the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) and the Achieving a Better Life Experience Act of 2014 (ABLE). This proposed rule is also necessary to make changes to payment policy and other related policies for Medicare Part B, Part D, and Medicare Advantage.

B. Overall Impact

We examined the impact of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (February 2, 2013), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). We estimate, as discussed in this section, that the PFS provisions included in this proposed rule would redistribute more than $100 million in 1 year. Therefore, we estimate that this rulemaking is "economically significant" as measured by the $100 million threshold, and hence also a major rule under the Congressional Review Act. Accordingly, we prepared an RIA that, to the best of our ability, presents the costs and benefits of the rulemaking. The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals, practitioners and most other providers and suppliers are small entities, either by nonprofit status or by having annual revenues that qualify for small business status under the Small Business Administration standards. (For details see the SBA's Web site at *http://www.sba.gov/content/table-small-business-size-standards* (refer to the 620000 series)). Individuals and states are not included in the definition of a small entity.

The RFA requires that we analyze regulatory options for small businesses and other entities. We prepare a regulatory flexibility analysis unless we certify that a rule would not have a significant economic impact on a substantial number of small entities. The analysis must include a justification concerning the reason action is being taken, the kinds and number of small entities the rule affects, and an explanation of any meaningful options that achieve the objectives with less significant adverse economic impact on the small entities.

Approximately 95 percent of practitioners, other providers, and suppliers are considered to be small entities, based upon the SBA standards. There are over 1 million physicians, other practitioners, and medical suppliers that receive Medicare payment under the PFS. Because many of the affected entities are small entities, the analysis and discussion provided in this section as well as elsewhere in this proposed rule is intended to comply with the RFA requirements.

In addition, section 1102(b) of the Act requires us to prepare an RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. We did not prepare an analysis for section 1102(b) of the Act because we determined, and the Secretary certified, that this proposed rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits on state, local, or tribal governments or on the private sector before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2016, that threshold is approximately $146 million. This proposed rule would impose no mandates on state, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. Since this regulation does not impose any costs on state or local governments, the requirements of Executive Order 13132 are not applicable.

We prepared the following analysis, which together with the information provided in the rest of this preamble, meets all assessment requirements. The analysis explains the rationale for and purposes of this proposed rule; details the costs and benefits of the rule; analyzes alternatives; and presents the measures we would use to minimize the burden on small entities. As indicated elsewhere in this proposed rule, we are proposing to implement a variety of changes to our regulations, payments, or payment policies to ensure that our payment systems reflect changes in medical practice and the relative value of services, and to implement statutory provisions. We provide information for each of the policy changes in the relevant sections of this proposed rule. We are unaware of any relevant federal rules that duplicate, overlap, or conflict with this proposed rule. The relevant sections of this proposed rule contain a description of significant alternatives if applicable.

C. Changes in Relative Value Unit (RVU) Impacts

1. Resource-Based Work, PE, and MP RVUs

Section 1848(c)(2)(B)(ii)(II) of the Act requires that increases or decreases in RVUs may not cause the amount of expenditures for the year to differ by more than $20 million from what expenditures would have been in the absence of these changes. If this threshold is exceeded, we make adjustments to preserve budget neutrality.

Our estimates of changes in Medicare expenditures for PFS services compare payment rates for CY 2016 with proposed payment rates for CY 2017 using CY 2015 Medicare utilization. The payment impacts in this proposed rule reflect averages by specialty based on Medicare utilization. The payment impact for an individual physician could vary from the average and would depend on the mix of services the practitioner furnishes. The average percentage change in total revenues would be less than the impact displayed here because practitioners and other entities generally furnish services to both Medicare and non-Medicare patients. In addition, practitioners and other entities may receive substantial Medicare revenues for services under other Medicare payment systems. For instance, independent laboratories receive approximately 83 percent of their Medicare revenues from clinical laboratory services that are paid under the Clinical Lab Fee Schedule.

The annual update to the PFS conversion factor (CF) was previously calculated based on a statutory formula; for details about this formula, we refer readers to the CY 2015 PFS final rule with comment period (79 FR 67741 through 67742). Section 101(a) of the MACRA repealed the previous statutory update formula amended section 1848(d) of the Act to specify the update adjustment factors for calendar years 2015 and beyond. For 2017, the specified update is 0.5 percent.

We note that section 220(d) of the PAMA added a new paragraph at section 1848(c)(2)(O) of the Act to establish an annual target for reductions in PFS expenditures resulting from adjustments to relative values of misvalued codes. Under section 1848(c)(2)(O)(ii) of the Act, if the net reduction in expenditures for the year is equal to or greater than the target for the year, reduced expenditures attributable to such adjustments shall be redistributed in a budget-neutral manner within the PFS in accordance with the existing budget neutrality requirement under section 1848(c)(2)(B)(ii)(II) of the Act. Section 1848(c)(2)(O)(iii) of the Act specifies that, if the estimated net reduction in PFS expenditures for the year is less than the target for the year, an amount equal to the target recapture amount shall not be taken into account when applying the budget neutrality requirements specified in section 1848(c)(2)(B)(ii)(II) of the Act. We estimate the CY 2017 net reduction in expenditures resulting from proposed adjustments to relative values of misvalued codes to be 0.51 percent. Since, if finalized, this amount would exceed the 0.5 percent target established by the Achieving a Better Life Experience Act of 2014 (ABLE) (Division B of Pub. L. 113–295, enacted December 19, 2014), there is no residual difference between the target for the year and the estimated net reduction in expenditures (the "Target Recapture Amount") by which to reduce payments made under the PFS. As a result, we estimate that the proposed PFS rates would not produce a CY 2017 Target Recapture Amount applicable to the CY 2017 CF. However, we note that the final Target Recapture Amount will be calculated based on the adjustments to misvalued codes as finalized in the CY 2017 PFS Final Rule.

Effective January 1, 2012, we implemented an MPPR of 25 percent on the professional component (PC) of advanced imaging services. Section 502(a)(2)(A) of the Consolidated Appropriations Act of 2016 (Pub. L 114–113, enacted on December 18, 2015) added a new section 1848(b)(10) of the Act which revises the multiple procedure payment reduction on the professional component of imaging services from 25 percent to 5 percent, effective January 1, 2017. Section 502(a)(2)(B) added a new subclause at section 1848(c)(2)(B)(v)(XI) which exempts the MPPR reductions attributable to the new 5 percent MPPR on the PC of imaging from the PFS budget neutrality provision. However, the provision does not exempt the change from the 25 percent MPPR from PFS budget neutrality. Therefore, for CY 2017 we must calculate PFS rates in a manner that exempts the 5 percent MPPR from budget neutrality but ensures that the elimination of the 25 percent MPPR is included in PFS budget neutrality. We note that the application of the 25 percent MPPR has been applied in a budget neutral fashion to date.

The CY 2017 proposed PFS rates exclude the 5 percent MPPR for the professional component of imaging services by calculating the rates as if the discount does not occur, consistent with our approach to other discounts that occur outside of PFS budget neutrality. In order to implement the change from the 25 percent discount in 2016 to the 5 percent discount in 2017 within PFS budget neutrality, we measured the difference in total RVUs for the relevant services assuming an MPPR of 25 percent and the total RVUs for the same services without an MPPR and then applied that difference as an adjustment to the conversion factor to account for the increased expenditures attributable to the change, within PFS budget neutrality. This approach is consistent with the statutory provision that requires the 5 percent MPPR to be implemented outside of PFS budget neutrality.

To calculate the proposed conversion factor for this year, we multiply the product of the current year conversion factor and the update adjustment factor by the budget neutrality adjustment and the imaging MPPR adjustment described in the preceding paragraphs. We estimate the CY 2017 PFS conversion factor to be 35.7751, which reflects the budget neutrality adjustment, the 0.5 percent update adjustment factor specified under section 1848(d)(18) of the Act, and a the adjustment due to the non-budget neutral 5 percent MPPR for the professional component of imaging services. We did not need to apply an adjustment for atarget recapture for the reasons described above. We estimate the CY 2017 anesthesia conversion factor to be 21.9756, which reflect the same overall PFS adjustments.

TABLE 41—CALCULATION OF THE PROPOSED CY 2017 PFS CONVERSION FACTOR

Conversion factor in effect in CY 2016		35.8043
Update Factor	0.50 percent (1.0050)	
CY 2017 RVU Budget Neutrality Adjustment	−0.51 percent (0.9949)	
CY 2017 Target Recapture Amount	0 percent (1.0000)	
CY 2017 Imaging MPPR Adjustment	−0.07 percent (0.9993)	

TABLE 41—CALCULATION OF THE PROPOSED CY 2017 PFS CONVERSION FACTOR—Continued

Conversion factor in effect in CY 2016		35.8043
CY 2017 Conversion Factor		35.7751

TABLE 42—CALCULATION OF THE PROPOSED CY 2017 ANESTHESIA CONVERSION FACTOR

CY 2016 national average anesthesia conversion factor		21.9935
Update Factor	0.50 percent (1.0050)	
CY 2017 RVU Budget Neutrality Adjustment	−0.51 percent (0.9949)	
CY 2017 Target Recapture Amount	0 percent (1.0000)	
CY 2017 Imaging MPPR Adjustment	−0.07 percent (0.9993)	
CY 2017 Conversion Factor		21.9756

Table 43 shows the payment impact on PFS services of the proposals contained in this proposed rule. To the extent that there are year-to-year changes in the volume and mix of services provided by practitioners, the actual impact on total Medicare revenues would be different from those shown in Table 43 (CY 2017 PFS Estimated Impact on Total Allowed Charges by Specialty). The following is an explanation of the information represented in Table 43.

- *Column A (Specialty):* Identifies the specialty for which data is shown.
- *Column B (Allowed Charges):* The aggregate estimated PFS allowed charges for the specialty based on CY 2015 utilization and CY 2016 rates. That is, allowed charges are the PFS amounts for covered services and include coinsurance and deductibles (which are the financial responsibility of the beneficiary). These amounts have been summed across all services furnished by physicians, practitioners, and suppliers within a specialty to arrive at the total allowed charges for the specialty.
- *Column C (Impact of Work RVU Changes):* This column shows the estimated CY 2017 impact on total allowed charges of the changes in the work RVUs, including the impact of changes due to potentially misvalued codes.
- *Column D (Impact of PE RVU Changes):* This column shows the estimated CY 2017 impact on total allowed charges of the changes in the PE RVUs.
- *Column E (Impact of RVU Changes):* This column shows the estimated CY 2017 impact on total allowed charges of the changes in the MP RVUs, which are primarily driven by the required five-year review and update of MP RVUs.
- *Column F (Combined Impact):* This column shows the estimated CY 2017 combined impact on total allowed charges of all the changes in the previous columns. Column F may not equal the sum of columns C, D, and E due to rounding.

TABLE 43—CY 2017 PFS ESTIMATED IMPACT ON TOTAL ALLOWED CHARGES BY SPECIALTY *

Specialty (A)	Allowed Charges (mil) (B)	Impact of Work RVU Changes (C)	Impact of PE RVU Changes (D)	Impact of MP RVU Changes (E)	Combined Impact ** (F)
TOTAL	$89,467	0%	0%	0%	0%
ALLERGY/IMMUNOLOGY	230	0	1	0	2
ANESTHESIOLOGY	1,977	0	−1	0	0
AUDIOLOGIST	61	0	0	0	1
CARDIAC SURGERY	322	0	0	0	0
CARDIOLOGY	6,461	0	0	0	1
CHIROPRACTOR	779	0	0	0	0
CLINICAL PSYCHOLOGIST	727	0	0	0	0
CLINICAL SOCIAL WORKER	601	0	0	0	0
COLON AND RECTAL SURGERY	160	0	0	0	0
CRITICAL CARE	308	0	0	0	0
DERMATOLOGY	3,305	0	0	0	1
DIAGNOSTIC TESTING FACILITY	750	0	−2	0	−2
EMERGENCY MEDICINE	3,133	0	0	0	0
ENDOCRINOLOGY	458	1	1	0	2
FAMILY PRACTICE	6,087	1	1	0	3
GASTROENTEROLOGY	1,744	0	0	0	−1
GENERAL PRACTICE	451	1	1	0	2
GENERAL SURGERY	2,157	0	0	0	0
GERIATRICS	211	1	1	0	2
HAND SURGERY	182	0	0	0	0
HEMATOLOGY/ONCOLOGY	1,746	1	1	0	2
INDEPENDENT LABORATORY	701	0	−5	0	−5
INFECTIOUS DISEASE	652	0	0	0	1
INTERNAL MEDICINE	10,849	1	1	0	2
INTERVENTIONAL PAIN MGMT	767	1	0	0	0
INTERVENTIONAL RADIOLOGY	315	−1	−5	0	−7
MULTISPECIALTY CLINIC/OTHER PHYS	128	1	1	0	1

TABLE 43—CY 2017 PFS ESTIMATED IMPACT ON TOTAL ALLOWED CHARGES BY SPECIALTY *—Continued

Specialty (A)	Allowed Charges (mil) (B)	Impact of Work RVU Changes (C)	Impact of PE RVU Changes (D)	Impact of MP RVU Changes (E)	Combined Impact ** (F)
NEPHROLOGY	2,205	0	−1	0	−1
NEUROLOGY	1,514	1	1	0	1
NEUROSURGERY	784	−1	0	0	−1
NUCLEAR MEDICINE	47	0	0	0	0
NURSE ANES/ANES ASST	1,211	0	0	0	0
NURSE PRACTITIONER	2,974	1	1	0	2
OBSTETRICS/GYNECOLOGY	647	0	1	0	1
OPHTHALMOLOGY	5,493	0	−2	0	−2
OPTOMETRY	1,213	0	−1	0	−1
ORAL/MAXILLOFACIAL SURGERY	48	0	0	0	0
ORTHOPEDIC SURGERY	3,685	0	0	0	0
OTHER	26	0	0	0	0
OTOLARNGOLOGY	1,208	0	0	0	0
PATHOLOGY	1,127	0	−2	0	−2
PEDIATRICS	61	1	1	0	2
PHYSICAL MEDICINE	1,062	0	0	0	1
PHYSICAL/OCCUPATIONAL THERAPY	3,395	0	0	0	1
PHYSICIAN ASSISTANT	1,959	0	1	0	1
PLASTIC SURGERY	374	0	0	0	0
PODIATRY	1,954	0	0	0	1
PORTABLE X–RAY SUPPLIER	104	0	−1	0	−1
PSYCHIATRY	1,250	1	1	0	1
PULMONARY DISEASE	1,759	0	0	0	1
RADIATION ONCOLOGY	1,720	0	0	0	0
RADIATION THERAPY CENTERS	43	0	−1	0	−1
RADIOLOGY	4,670	0	−1	0	−1
RHEUMATOLOGY	536	1	1	0	2
THORACIC SURGERY	356	0	0	0	0
UROLOGY	1,764	−1	0	0	−1
VASCULAR SURGERY	1,045	0	−2	0	−2

** Column F may not equal the sum of columns C, D, and E due to rounding.

2. CY 2017 PFS Impact Discussion

a. Changes in RVUs

The most widespread specialty impacts of the proposed RVU changes are generally related to the proposed changes to RVUs for specific services resulting from the Misvalued Code Initiative, including proposed RVUs for new and revised codes. Several specialties, including interventional radiology and independent labs, would experience significant decreases to overall payments for services that they frequently furnish as a result of revisions to the coding structure or the proposed inputs used to develop RVUs for the codes that describe particular services. Other specialties, including endocrinology and family practice, would experience significant increases to payments for similar reasons.

b. Impact

Column F of Table 43 displays the estimated CY 2017 impact on total allowed charges by specialty of all the RVU changes. A table shows the estimated impact on total payments for selected high volume procedures of all of the changes is available under "downloads" on CY 2017 PFS proposed rule Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/*. We selected these procedures for sake of illustration from among the most commonly furnished by a broad spectrum of specialties. The change in both facility rates and the nonfacility rates are shown. For an explanation of facility and nonfacility PE, we refer readers to Addendum A on the CMS Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/*.

D. Effect of Proposed Changes in Telehealth List

As discussed in section II.I. of this proposed rule, we proposed to add several new codes to the list of Medicare telehealth services. Although we expect these changes to increase access to care in rural areas, based on recent utilization of similar services already on the telehealth list, we estimate no significant impact on PFS expenditures from the additions relative to overall PFS expenditures.

E. Geographic Practice Cost Indices (GPCIs)

Based upon statutory requirements, we are proposing new GPCIs for each Medicare payment locality. The proposed GPCIs incorporate updated data and cost share weights as discussed in II.E. The Act requires that updated GPCIs be phased in over two years. Addendum D shows the estimated effects of the revised GPCIs on area GAFs for the transition year (CY 2017) and the fully implemented year (CY 2018). The GAFs reflect the use of the updated underlying GPCI data, and the cost share weights remain unchanged from the previous (seventh) GPCI update. The GAFs are a weighted composite of each area's work, PE and malpractice expense GPCIs using the national GPCI cost share weights. While we do not actually use the GAFs in computing the fee schedule payment for a specific service, they are useful in comparing overall areas costs and payments. The actual effect on payment for any actual service will deviate from the GAF to the extent that the proportions of work, PE and malpractice expense RVUs for the service differ from those of the GAF.

The most significant changes occur in 19 non-California payment localities, where the fully implemented (CY 2018) GAF moves up by more than 1 percent (14 payment localities) or down by more than 2 percent (5 payment localities).

F. Other Provisions of the Proposed Regulation

1. Proposal To Change Direct Supervision Requirement to General Supervision for CCM Services Furnished Incident to RHCs and FQHCs

In section III.A., we proposed to revise § 405.2413(a)(5) and § 405.2415(a)(5) to state that services and supplies furnished incident to TCM and CCM services can be furnished under general supervision of a RHC or FQHC practitioner. In section III.A., we proposed revising the CCM requirements for RHCs and FQHCs to be consistent with the proposed revisions to the CCM requirements for practitioners billing under the PFS. These proposed revisions will allow RHCs and FQHCs to provide TCM and CCM services at the level that was projected when the programs were authorized and therefore no impact on spending is expected.

As outlined in section III.A., we proposed to change the direct supervision requirement to a general supervision for CCM services furnished incident to RHCs and FQHCs. This regulatory change was already made for CCM services furnished by practitioners billing the PFS, and changes to RHC and FQHC regulations have no impact on regulations for practitioners billing under the PFS. The impact on RHCs and FQHCs in 2017 is negligible, as estimates are rounded to the nearest 5 million and 2017 was too small of an impact to have a notable effect on the estimate.

2. FQHC-Specific Market Basket

As discussed in section III.B of this proposed rule, we are proposing to create a 2013-based FQHC market basket to update the FQHC PPS base payment rate. Table 44 shows the 5-year and 10-year fiscal cost estimates from switching from a MEI-adjusted base payment rate to a FQHC PPS market basket-adjusted base payment rate. This was determined by compiling data on historical FQHC spending, projecting it forward, and creating two separate baselines. The first baseline assumed an MEI price update and the second baseline assumed an FQHC specific market basket price update which was created by the Office of the Actuary within CMS. The utilization of services was held constant between the two baselines, and therefore, the impact table specifically captures the change in price from now growing at an FQHC MB update relative to how it was growing at the MEI updates. We estimate that this would cost approximately 170 million dollars over 10 years from FY 2017–2026, 35 million of which would be paid for through beneficiary premiums and the remaining 135 million would be paid for through Part B.

TABLE 44: 5-Year and 10-Year Fiscal Cost Estimates from Switching from an MEI-adjusted Base Payment Rate to a FQHC PPS Market Basket-adjusted Base Payment Rate

Estimate [in millions]	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	5-year impact 2017 - 2021	10-year impact 2017 - 2026
FY Cash Impact (with MC)	-	-	-	-	-	-	-	-	-	-	-	-	-
Part B													
Benefits	-	-	5	10	10	15	15	20	25	30	40	**40**	**170**
Premium Offset	-	-	-	-	-	(5)	(5)	(5)	(5)	(5)	(10)	**(5)**	**(35)**
Total Part B	-	-	5	10	10	10	10	15	20	25	30	**35**	**135**

3. Appropriate Use Criteria for Advanced Diagnostic Imaging Services

We are proposing and requesting public comment on clinical decision support mechanism (CDSM) requirements as well as an application process that CDSM developers must comply with for their mechanisms to be specified as qualified under this program. These proposals would not impact CY 2017 physician payments under the PFS.

4. Reports of Payments or Other Transfers of Value to Covered Recipients

We are soliciting comments to inform future rulemaking. We do not intend to finalize any requirements directly as a result of this proposed rule; so there is no impact to CY 2017 physician payments under the PFS.

5. Release of Part C Medicare Advantage Bid Pricing Data and Part C and Part D Medical Loss Ratio (MLR) Data

Under section III.E. of the preamble of this proposed rule, we are proposing to revise the existing regulations by adding § 422.272 to provide for an annual public release of MA bid pricing data (with specified exceptions from release). The annual release would occur after the first Monday in October and would contain MA bid pricing data that was accepted or approved by CMS for a contract year at least 5 years prior to the upcoming calendar year. Under current authority at § 422.254, MA organizations (MAOs) are required to submit bid pricing data to CMS each year for MA plans they wish to offer in the upcoming contract year (calendar year).

In addition, the proposed rule adds § 422.2490 for Part C and § 423.2490 for Part D to provide for an annual public release of Part C and Part D medical loss ratio (MLR) data (with specified exceptions from release). This annual release would occur no sooner than 18 months after the end of the contract year for which MLR data was reported to CMS. Starting with contract year 2014, each MAO or Part D sponsor that fails to spend at least 85 percent of revenue received under an MA or Part D contract on incurred claims and quality improving activities must remit the difference to the government. Under current authority at § 422.2460 and § 423.2460, each year MAOs and Part D sponsors must submit an MLR Report to CMS, which includes the data needed by the MAO or Part D sponsor to calculate and verify the MLR and remittance amount, if any, for each contract.

We are proposing to add regulatory language to authorize CMS' release of such data to the public. We have determined that the proposed regulatory amendments do not impose any mandatory costs on the public or entities that seek to download and use the released data. We expect that this data will be available to the public from the CMS Web site (*https://www.cms.gov/*). The public may elect to download the data files, which will not impose mandatory costs on any user. Therefore, we have determined that there are not any economically significant effects of the proposed provisions. We also have determined that the proposed regulatory amendments would not impose a burden on the entity requesting or downloading data files.

6. Prohibition on Billing Qualified Medicare Beneficiary Individuals for Medicare Cost-Sharing

We are restating information to inform providers to take steps to educate themselves and their staff about QMB billing prohibitions and to exempt QMB individuals from Medicare cost-sharing billing and related collection efforts. Therefore, there is no impact to CY 2017 physician payments under the PFS.

7. Recoupment or Offset of Payments to Providers Sharing the Same Taxpayer Identification Number

This proposed rule implements section 1866(j) of the Act which grants the Secretary the authority to authority to make any necessary adjustments to the payments of an applicable provider of services or supplier who shares a TIN with an obligated provider of services or supplier that has an outstanding Medicare overpayment. The Secretary is authorized to adjust the payments of such applicable provider, regardless of whether that applicable provider is assigned a different Medicare billing number or National Provider Identifier (NPI) number from the obligated provider with the outstanding Medicare overpayment. The concept of offsetting or recouping payments of providers sharing a TIN to satisfy a Medicare overpayment is analogous to Treasury's current practice of offsetting against entities that share a TIN to collect Medicare overpayments. This proposed rule would help support our efforts to safeguard the Medicare Trust Funds by collecting its own overpayments more quickly and reducing the accounts receivable delinquency rates reported in the Treasury Report on Receivables. This proposed rule also helps the obligated provider because we would collect the overpayments more quickly; thus reducing the additional interest assessments that would continue on the provider's outstanding delinquent balance until paid in full. Therefore, there is no impact to CY 2017 physician payments under the PFS.

8. Provider Enrollment Part C Program

This proposed rule would require that providers and suppliers must be enrolled in Medicare in approved status in order to render services to beneficiaries in the Medicare Advantage program. This proposed rule will not have a significant economic impact on a substantial number of small businesses because the number not enrolled in Medicare appears to be small in comparison to the general population of providers. The completion of the Form CMS–855 (as explained in section III) would be required very infrequently, in many cases either only one time or once every several years. Also, the hour and cost burden per provider or supplier will not pose a significant burden on a provider and supplier, especially when considering the overall revenue that providers and suppliers receive per year. We thus do not believe our proposal would impact a substantial number of small businesses.

Virtually all of the quantifiable costs associated with this proposed rule involve the paperwork burden to providers and suppliers (see section IV. of this proposed rule). The estimates presented in this section do not address the potential financial benefits of this proposed rule from the standpoint of the rule's effectiveness in preventing or deterring certain providers from enrolling in or maintaining their enrollment in Medicare. We simply have no means of quantifying these benefits in monetary terms.

There are three main uncertainties associated with this proposed rule. First, we are uncertain as to the number of providers and suppliers that would be required to enroll in Medicare under § 422.222. Second, we cannot estimate the savings in fraud and abuse prevention that would accrue from this rule. Third, since we have no systematic method to know how many FDRs may be used by MA or MA–PD organizations to deliver services to Medicare beneficiaries, therefore, we cannot estimate the possible impact to FDRs.

9. Proposed Expansion of the Diabetes Prevention Program (DPP) Model

In this rule, we propose to expand the Diabetes Prevention Program (DPP) Model in accordance with section 1115A(c) of the Act, and we propose to refer to this expanded model as the Medicare Diabetes Prevention Program (MDPP). We propose that MDPP will become effective January 1, 2018, and CMS will continue to test and evaluate MDPP as finalized. In the future, CMS will assess whether the nationwide implementation of the MDPP is continuing to either reduce Medicare spending without reducing quality of care or improve the quality of patient care without increasing spending, and could modify the nationwide MDPP as appropriate. In this proposed rule, we propose a basic framework for the MDPP. If finalized, we will engage in additional rulemaking, likely within the next year, to establish specific requirements of the MDPP. The comments received from this proposed rule will inform key design parameters of the MDPP. Modifications to the proposed MDPP could result in changes to our current financial projections and therefore affect economic impact estimates of MDPP. For these reasons, it is premature to provide an impact statement at this time. We intend to provide an impact statement in future rulemaking.

10. Medicare Shared Savings Program

We are proposing certain rules having to do with ACO quality reporting: (1) We are proposing conforming changes to align with the policies included in the QPP proposed rule, including changes to the quality measure set; (2) we are proposing to streamline the quality validation audit process and use the results to modify an ACO's overall quality score; (3) we are proposing revisions to references to the Quality Performance Standard and Minimum Attainment; (4) we are clarifying that measures calculated as ratios are excluded from use of flat percentages when such benchmarks appear "clustered" or "topped out"; and (5) we are proposing to modify our PQRS alignment rules to permit flexibility for EPs to report quality data to PQRS to avoid the PQRS and VM downward adjustments for 2017 and 2018 in cases where an ACO fails to report on their behalf. In addition, we are proposing updates to the assignment methodology to include beneficiaries who identify ACO professionals as being responsible for coordinating their overall care.

We are also proposing additional beneficiary protections when ACOs in Track 3 make use of the SNF 3-day rule waiver. Finally, we are proposing certain technical changes and clarifications related to reconciliation for ACOs that fall below 5,000 assigned beneficiaries and related to our policies for consideration of claims billed by merged and acquired TINs.

Because the proposed policies are not expected to substantially change the quality reporting burden for ACOs participating in the Shared Savings Program and their ACO participants or change the financial calculations, we do not anticipate any impact for these proposals.

11. Value-Based Payment Modifier and the Physician Feedback Program

Section 1848(p) of the Act requires that we establish a value-based payment modifier (VM) and apply it to specific physicians and groups of physicians the Secretary determines appropriate starting January 1, 2015 and to all physicians and groups of physicians by January 1, 2017. Section 1848(p)(4)(C) of the Act requires the VM to be budget neutral. Budget-neutrality means that, in aggregate, the increased payments to high performing physicians and groups of physicians equal the reduced payments to low performing physicians and groups of physicians.

In the CY 2015 PFS final rule with comment period (79 FR 67936 and 67941 through 67942), we established that, beginning with the CY 2017 payment adjustment period, the VM will apply to physicians in groups with two or more EPs and to physicians who are solo practitioners based on the applicable performance period, including physicians that participate in an ACO under the Shared Savings Program. In the CY 2014 PFS final rule with comment period (78 FR 74771 through 74772), we established CY 2015 as the performance period for the VM that will be applied to payments during CY 2017. In CY 2017, the VM will be waived for groups and solo practitioners, as identified by their TIN, if at least one EP who billed for Medicare PFS items and services under the TIN during 2015 participated in the Pioneer ACO Model or the Comprehensive Primary Care initiative in 2015 (80 FR 71288).

In the CY 2015 PFS final rule with comment period (79 FR 67938 through 67939), we adopted a two-category approach for the CY 2017 VM based on participation in the PQRS by groups and solo practitioners. Category 1 will include those groups that meet the criteria to avoid the PQRS payment adjustment for CY 2017 as a group practice participating in the PQRS GPRO in CY 2015. We finalized in the CY 2016 PFS final rule with comment period (80 FR 71280 through 71281) that, for the CY 2017 VM, Category 1 will also include groups that have at least 50 percent of the group's EPs meet the criteria to avoid the PQRS payment adjustment for CY 2017 as individuals. In determining whether a group will be included in Category 1, we will consider whether the 50 percent threshold has been met regardless of whether the group registered to participate in the PQRS GPRO in CY 2015. Lastly, Category 1 will include those solo practitioners that meet the criteria to avoid the PQRS payment adjustment for CY 2017 as individuals.

For groups and solo practitioners that participated in an ACO under the Shared Savings Program in CY 2015, they are considered to be Category 1 for the CY 2017 VM if the ACO in which they participated successfully reported on quality measure via the GPRO Web Interface in CY 2015 (79 FR 67946). As discussed in sections III.I. and III.L.1.e. of this proposed rule, we are proposing to remove the prohibition on EPs who are part of a group or solo practitioner that participates in a Shared Savings Program ACO, for purposes of PQRS reporting for the CY 2017 and CY 2018 payment adjustments, to report outside the ACO. In section III.L.3.b. of this proposed rule, we are proposing for the CY 2017 payment adjustment period, if a Shared Savings Program ACO did not successfully report quality data as required by the Shared Savings Program under § 425.504 for the CY 2017 PQRS payment adjustment, then we propose to use the data reported to the PQRS by the EPs (as a group using one of the group registry, QCDR, or EHR reporting options or as individuals using the registry, QCDR, or EHR reporting option) under the participant TIN) outside of the ACO during the secondary PQRS reporting period to determine whether the TIN would fall in Category 1 or Category 2 under the VM. We are proposing that groups that meet the criteria to avoid PQRS payment adjustment for CY 2018 as a group practice participating in the PQRS GPRO (using one of the group registry, QCDR, or EHR reporting options) or have at least 50 percent of the group's EPs meet the criteria to avoid the PQRS payment adjustment for CY 2018 as individuals (using the registry, QCDR, or EHR reporting option), based on data submitted outside the ACO and during the secondary PQRS reporting period, would be included in Category 1 for the CY 2017 VM. We are also proposing that solo practitioners that meet the criteria to avoid the PQRS payment adjustment for CY 2018 as individuals using the registry, QCDR, or EHR reporting option, based on data submitted outside the ACO and during the secondary PQRS reporting period, would be included in Category 1 for the CY 2017 VM. Category 2 would include those groups and solo practitioners subject to the CY 2017 VM that participate in a Shared Savings Program ACO and do not fall within Category 1.

The CY 2017 VM payment adjustment amount for groups and solo practitioners in Category 2 is −4.0 percent for groups of physicians with 10 or more EPs and −2.0 percent for groups of physicians with between 2 to 9 EPs and physician solo practitioners.

In the CY 2015 PFS final rule with comment period (79 FR 67939 through 67941), we finalized that quality-tiering, which is the methodology for evaluating performance on quality and cost measures for the VM, will apply to all groups of physicians and physician solo practitioners in Category 1 for the VM for CY 2017. However, groups of physicians with between 2 to 9 EPs and physician solo practitioners will be subject only to upward or neutral adjustments derived under quality-tiering, while groups of physicians with 10 or more EPs will be subject to upward, neutral, or downward adjustments derived under quality-tiering. That is, groups of physicians with between 2 to 9 EPs and physician solo practitioners in Category 1 would be held harmless from any downward adjustments derived under quality-tiering for the CY 2017 VM.

Under the quality-tiering methodology, each group and solo practitioner's quality and cost composites will be classified into high, average, and low categories depending upon whether the composites are at least one standard deviation above or below the mean and statistically different from the mean. We will compare their quality of care composite classification with the cost composite classification to determine their VM adjustment for the CY 2017 payment adjustment period according to the amounts in Tables 45 and 46.

TABLE 45—CY 2017 VM PAYMENT ADJUSTMENT AMOUNTS UNDER QUALITY-TIERING FOR GROUPS OF PHYSICIANS WITH TWO TO NINE EPS AND PHYSICIAN SOLO PRACTITIONERS

Cost/quality	Low quality	Average quality	High quality
Low cost	+0.0%	*+1.0x	*+2.0x
Average cost	+0.0%	+0.0%	*+1.0x

TABLE 45—CY 2017 VM PAYMENT ADJUSTMENT AMOUNTS UNDER QUALITY-TIERING FOR GROUPS OF PHYSICIANS WITH TWO TO NINE EPS AND PHYSICIAN SOLO PRACTITIONERS—Continued

Cost/quality	Low quality	Average quality	High quality
High cost	+0.0%	+0.0%	+0.0%

* Groups and solo practitioners eligible for an additional +1.0x if reporting measures and average beneficiary risk score is in the top 25 percent of all beneficiary risk scores, where 'x' represents the upward payment adjustment factor.

TABLE 46—CY 2017 VM PAYMENT ADJUSTMENT AMOUNTS UNDER QUALITY-TIERING FOR GROUPS OF PHYSICIANS WITH TEN OR MORE EPS

Cost/quality	Low quality	Average quality	High quality
Low cost	+0.0%	* +2.0x	* +4.0x
Average cost	−2.0%	+0.0%	* +2.0x
High cost	−4.0%	−2.0%	+0.0%

* Groups eligible for an additional +1.0x if reporting measures and average beneficiary risk score is in the top 25 percent of all beneficiary risk scores, where 'x' represents the upward payment adjustment factor.

Under the quality-tiering methodology, for groups and solo practitioners that participated in a Shared Savings ACO that successfully reports quality data for CY 2015, the cost composite will be classified as "Average" and the quality of care composite will be based on ACO-level quality measures. We will compare their quality of care composite classification with the "Average" cost composite classification to determine their VM adjustment for the CY 2017 payment adjustment period according to the amounts in Tables 45 and 46.

We are proposing in section III.M.3.b. of this proposed rule, for groups and solo practitioners that participate in a Shared Savings Program ACO that did not successfully report quality data for CY 2015 and are in Category 1 as a result of reporting quality data to the PQRS outside of the ACO using the secondary PQRS reporting period, we are proposing to classify their quality composite for the VM for the CY 2017 payment adjustment period as "average quality." Their cost composite will be classified as "average cost" (79 FR 67943).

To ensure budget neutrality, we first aggregate the downward payment adjustments in Tables 45 and 46 for those groups and solo practitioners in Category 1 with the automatic downward payment adjustments of −2.0 percent or −4.0 percent for groups and solo practitioners subject to the VM that fall within Category 2. Using the aggregate downward payment adjustment amount, we then calculate the upward payment adjustment factor (x). We plan to incorporate assumptions about the number of physicians in groups and physician solo practitioners in the ACOs that did not successfully report their CY 2015 quality data whose status could potentially change from Category 2 to Category 1 if the group or solo practitioner satisfactorily report their 2016 data during the secondary PQRS reporting period. Additionally, as we had done when calculating the upward payment adjustment factor for the 2016 VM, we will also incorporate adjustments made for estimated changes in physician behavior (*i.e.*, changes in the volume and/or intensity of services delivered and shifting of services to TINs that receive higher VM adjustments) and estimated impact of pending PQRS and VM informal reviews. These calculations will be done after the performance period has ended.

At the time of this proposed rule, we have not completed the analysis of the impact of the VM in CY 2017 on physicians in groups with 2 or more EPs and physician solo practitioners based on their performance in CY 2015. In the CY 2017 PFS final rule with comment period, we will present the number of groups of physicians and physician solo practitioners that will be subject to the VM in CY 2017.

12. Physician Self-Referral Updates

The physician self-referral update provisions are discussed in section III.M of this proposed rule. We are re-proposing regulatory provisions prohibiting certain per-unit of service compensation formulas for determining rental charges in the exceptions for the rental of office space, rental of equipment, fair market value compensation, and indirect compensation arrangements. These provisions are necessary to protect against potential abuses such as overutilization and anti-competitive behavior. We believe that most parties comply with these regulatory provisions since they originally became effective on October 1, 2009, and the re-proposed regulations text is identical to the existing regulations text. Therefore, we do not believe that the proposals will have a significant burden.

G. Alternatives Considered

This proposed rule contains a range of policies, including some provisions related to specific statutory provisions. The preceding preamble provides descriptions of the statutory provisions that are addressed, identifies those policies when discretion has been exercised, presents rationale for our final policies and, where relevant, alternatives that were considered. For purposes of the payment impact on PFS services of the proposals contained in this proposed rule, we presented the estimated impact on total allowed charges by specialty. The alternatives we considered, as discussed in the preceding preamble sections, would result in different proposed payment rates, and therefore result in different estimates than those shown in Table 43 (CY 2017 PFS Estimated Impact on Total Allowed Charges by Specialty). For example, the estimated increases to primary care specialties would be lessened without the proposals to revise payment policies for certain care management and patient-specific services as described in section II.E. However, because PFS rates are based on relative value units, the proposed rates reflect all of the proposed changes and eliminating some of the proposed changes might have multi-faceted impacts on the payment rates for other services.

H. Impact on Beneficiaries

There are a number of changes in this proposed rule that would have an effect on beneficiaries. In general, we believe that many of these changes, including those intended to improve accuracy in payment through revisions to the inputs used to calculate payments under the PFS, would have a positive impact and improve the quality and value of care provided to Medicare beneficiaries. In particular, we believe that improving payment for primary care and care management services based more accurate assessment of patient needs and the resources involved in caring for them will benefit beneficiaries by improving care coordination and providing more effective treatment, particularly to those beneficiaries with behavioral health conditions and mobility-related disabilities.

Most of the aforementioned proposed policy changes could result in a change in beneficiary liability as relates to coinsurance (which is 20 percent of the fee schedule amount, if applicable for the particular provision after the beneficiary has met the deductible). To illustrate this point, as shown in our Public User File Impact on Payment for Selected Procedures table available on the CMS Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/*, the CY 2016 national payment amount in the nonfacility setting for CPT code 99203 (Office/outpatient visit, new) was $108.85, which means that in CY 2016, a beneficiary would be responsible for 20 percent of this amount, or $21.77. Based on this proposed rule, using the CY 2017 CF, the CY 2017 national payment amount in the nonfacility setting for CPT code 99203, as shown in the Impact on Payment for Selected Procedures table, is $108.76, which means that, in CY 2017, the proposed beneficiary coinsurance for this service would be $21.75.

As discussed in section III.B of this proposed rule, we are proposing that beginning on January 1, 2017, the FQHC base rate would be updated using a FQHC-specific market basket instead of using the MEI to more accurately reflect changes in the cost of furnishing FQHC services. This would result in a higher payment to FQHCs, and since coinsurance is 20 percent of the lesser of the FQHC's charge for the specific payment code or the PPS rate, beneficiary coinsurance would also increase. The FQHC market basket cost estimates in Table 44 includes a premium offset line which is the amount of cost that would be offset by the beneficiaries. The beneficiaries would pay approximately $5 million and $35 million over the 5 and 10 year projection windows.

I. Accounting Statement

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf*), in Table 47 (Accounting Statement), we have prepared an accounting statement. This estimate includes growth in incurred benefits from CY 2016 to CY 2017 based on the FY 2017 President's Budget baseline.

TABLE 47—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES

Category	Transfers
CY 2017 Annualized Monetized Transfers.	Estimated increase in expenditures of $0.5 billion for PFS CF update.
From Whom To Whom?	Federal Government to physicians, other practitioners and providers and suppliers who receive payment under Medicare.

TABLE 48—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED COSTS, TRANSFER, AND SAVINGS

Category	Transfers
CY 2017 Annualized Monetized Transfers of beneficiary cost coinsurance.	$0.1 billion.
From Whom to Whom?	Federal Government to Beneficiaries.

J. Conclusion

The analysis in the previous sections, together with the remainder of this preamble, provides an initial Regulatory Flexibility Analysis. The previous analysis, together with the preceding portion of this preamble, provides a Regulatory Impact Analysis. In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 405

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medical devices, Medicare, Reporting and recordkeeping requirements, Rural areas, X rays.

42 CFR Part 410

Health facilities, Health professions, Kidney diseases, Laboratories, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 411

Kidney diseases, Medicare, Physician referral, Reporting and recordkeeping requirements.

42 CFR Part 414

Administrative practice and procedure, Biologics, Drugs, Health facilities, Health professions, Kidney diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 417

Administrative practice and procedure, Grant programs—health, Health care, Health insurance, Health maintenance organizations (HMO), Loan programs—health, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 422

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 423

Administrative practice and procedure, Emergency medical services, Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 424

Emergency medical services, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 425

Administrative practice and procedure, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 460

Aged, Health care, Health records, Medicaid, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as set forth below:

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

■ 1. The authority citation for part 405 continues to read as follows:

Authority: Secs. 205(a), 1102, 1861, 1862(a), 1869, 1871, 1874, 1881, and 1886(k) of the Social Security Act (42 U.S.C. 405(a), 1302, 1395x, 1395y(a), 1395ff, 1395hh, 1395kk, 1395rr and 1395ww(k)), and sec. 353 of the Public Health Service Act (42 U.S.C. 263a).

■ 2. Section 405.373 is amended by—

■ a. Revising paragraphs (a) introductory text and (b).

■ b. Adding paragraph (f).

The revisions and addition read as follows:

§ 405.373 Proceeding for offset or recoupment.

(a) *General rule.* Except as specified in paragraphs (b) and (f) of this section, if the Medicare Administrative Contractor or CMS has determined that an offset or recoupment of payments under § 405.371(a)(2) should be put into effect, the Medicare Administrative Contractor must—

* * * * *

(b) Paragraph (a) of this section does not apply if the Medicare Administrative Contractor, after furnishing a provider a written notice of the amount of program reimbursement in accordance with § 405.1803, recoups payment under paragraph (c) of § 405.1803. (For provider rights in this circumstance, see §§ 405.1809, 405.1811, 405.1815, 405.1835, and 405.1843.)

* * * * *

(f) Paragraph (a) of this section does not apply in instances where the Medicare Administrative Contractor intends to offset or recoup payments to the applicable provider of services or supplier to satisfy an amount due from an obligated provider of services or supplier when the applicable and obligated provider of services or supplier share the same Taxpayer Identification Number.

■ 3. Section 405.2413 is amended by revising paragraph (a)(5) to read as follows:

§ 405.2413 Services and supplies incident to a physician's services.

(a) * * *

(5) Furnished under the direct supervision of a physician, except that services and supplies furnished incident to transitional care management and chronic care management services can be furnished under general supervision of a physician when these services or supplies are furnished by auxiliary personnel, as defined in § 410.26(a)(1) of this chapter.

* * * * *

■ 4. Section 405.2415 is amended by revising paragraph (a)(5) to read as follows:

§ 405.2415 Incident to services and direct supervision.

(a) * * *

(5) Furnished under the direct supervision of a nurse practitioner, physician assistant, or certified nurse-midwife, except that services and supplies furnished incident to transitional care management and chronic care management services can be furnished under general supervision of a nurse practitioner, physician assistant, or certified nurse-midwife, when these services or supplies are furnished by auxiliary personnel, as defined in § 410.26(a)(1) of this chapter.

* * * * *

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

■ 5. The authority citation for part 410 continues to read as follows:

Authority: Secs. 1102, 1834, 1871, 1881, and 1893 of the Social Security Act (42 U.S.C. 1302, 1395m, 1395hh, and 1395ddd).

■ 6. Section 410.26 is amended by—

■ a. Redesignating paragraphs (a)(3) through (7) as paragraphs (a)(4) through (8), respectively.

■ b. Adding new paragraph (a)(3).

■ c. Revising paragraph (b)(5).

The addition and revision reads as follows:

§ 410.26 Services and supplies incident to a physician's professional services: Conditions.

(a) * * *

(3) *General supervision* means the level of supervision by the physician (or other practitioner) of auxiliary personnel as defined in § 410.32(b)(3)(i).

* * * * *

(b) * * *

(5) In general, services and supplies must be furnished under the direct supervision of the physician (or other practitioner). Designated non-face-to-face care management services can be furnished under general supervision of the physician (or other practitioner) when these services or supplies are provided incident to the services of a physician (or other practitioner). The physician (or other practitioner) supervising the auxiliary personnel need not be the same physician (or other practitioner) who is treating the patient more broadly. However, only the supervising physician (or other practitioner) may bill Medicare for incident to services.

* * * * *

■ 7. Section 410.79 is added to subpart B to read as follows:

§ 410.79 Medicare diabetes prevention program expanded model: Conditions of coverage.

(a) Medicare Diabetes Prevention Program (MDPP) services will be available beginning on January 1, 2018.

(b) *Definitions.* For the purposes of this section the following definitions apply:

Baseline weight refers to the eligible beneficiary's body weight recorded during that beneficiary's first core session.

CDC-approved DPP core curriculum (core curriculum) refers to the content of the core sessions delivered during the first 6 months of the MDPP core benefit. All of the following 16 covered topics must be addressed:

(i) Welcome to the National Diabetes Prevention Program.

(ii) Self-Monitoring weight and food intake.

(iii) Eating less.

(iv) Healthy eating.

(v) Introduction to physical activity (Move those muscles).

(vi) Overcoming barriers to physical activity (Being active—A way of life).

(vii) Balancing calorie intake and output.

(viii) Environmental cues to eating and physical activity.

(ix) Problem solving.

(x) Strategies for healthy eating out.

(xi) Reversing negative thoughts.

(xii) Dealing with slips in lifestyle change.

(xiii) Mixing up your physical activity: Aerobic fitness.

(xiv) Social cues.

(xv) Managing stress.

(xvi) Staying motivated, Program wrap up.

CDC-approved DPP maintenance curriculum (maintenance curriculum) refers to the content of the core maintenance Sessions and ongoing maintenance sessions that are delivered as part of the MDPP core benefit and MDPP maintenance benefit, respectively. Core maintenance sessions and ongoing maintenance sessions must address one or more of the following topics:

(i) Welcome to the second phase of the program.

(ii) Healthy eating: Taking it one meal at a time.

(iii) Making active choices.

(iv) Balance your thoughts for long-term maintenance.

(v) Healthy eating with variety and balance.

(vi) Handling holidays, vacations, and special events.

(vii) More volume, fewer calories (adding water, vegetables, and fiber).

(viii) Dietary fats.

(ix) Stress and time management.

(x) Healthy cooking: Tips for food preparation and recipe modification.

(xi) Physical activity barriers.

(xii) Preventing relapse.

(xiii) Heart health.

(xiv) Life with Type 2 Diabetes.

(xv) Looking back and looking forward.

Coach means an individual person who furnishes MDPP services on behalf of an MDPP supplier as an employee or contractor.

Core maintenance sessions refers to the 6 months of monthly sessions delivered after the core sessions and are included in the core benefit. All core maintenance sessions must address different maintenance curriculum topics.

Core sessions refers to the 16 sessions that are furnished over a period of between 16 and 26 weeks that teach the core curriculum. Each of the core sessions must address one of the core curriculum topics, and all topics must be addressed by the end of the 16 sessions.

Diabetes Prevention Recognition Program (DPRP) means a program administered by the Centers for Disease Control and Prevention (CDC) that recognizes organizations that are able to deliver diabetes prevention program (DPP) services, follow the CDC-approved DPP curriculum, and meet CDC's performance standards and reporting requirements.

Evaluation weight refers to the beneficiary's body weight updated from the first core session and recorded before or during that beneficiary's final core session.

Full DPRP recognition refers to the designation from the CDC that an organization has consistently delivered CDC-approved DPP sessions, met CDC-performance standards and met CDC reporting requirements for at least 24–36 months following the organization's application to participate in the DPRP.

MDPP core benefit (core benefit) means a 12-month intensive behavioral change program that applies the core curriculum. The core benefit consists of 16 core sessions and 6 core maintenance sessions.

MDPP eligible beneficiary means an individual who satisfies the criteria defined in § 410.79(c)(1).

MDPP maintenance benefit (maintenance benefit) is furnished after core benefit has been completed and that covers beneficiaries who achieve and maintain the required minimum weight loss percentage.

MDPP services means the core sessions, core maintenance sessions, and ongoing maintenance sessions.

MDPP supplier means an entity that has either preliminary or full DPRP recognition and is enrolled in Medicare to bill for MDPP services.

Medicare Diabetes Prevention Program (MDPP) refers to an expanded model under section 1115A(c) of the Act that makes MDPP services available to beneficiaries who meet the eligibility requirements specified in paragraph (c)(1) of this section.

National Diabetes Prevention Program (DPP) means an evidence-based intervention targeted to individuals with pre-diabetes that is delivered in community and health care settings and administered by the Centers for Disease Control and Prevention (CDC).

Ongoing maintenance sessions refers to the monthly sessions furnished after the core benefit has been completed and that teach the maintenance curriculum.

Preliminary DPRP recognition refers to the designation from the CDC that an organization has delivered CDC-approved DPP sessions and has met CDC DPRP performance standards and reporting requirements for 12 consecutive months immediately following the organization's application to participate in the DPRP.

Required minimum weight loss means the percentage by which the evaluation weight is less than the baseline weight. The required minimum weight loss percentage is 5 percent.

(c) *General rule*—(1) *Beneficiary inclusion criteria.* Medicare Part B pays for MDPP services for beneficiaries who meet all of the following criteria:

(i) Are enrolled in Medicare Part B.

(ii) Have as of the date of attendance at the first core session a body mass index (BMI) of at least 25 if not self-identified as Asian and a BMI of at least 23 if self-identified as Asian.

(iii) Have within the 12 months prior to attending the first core session a hemoglobin A1c test with a value between 5.7 and 6.4 percent, a fasting plasma glucose of 110–125 mg/dL, or a 2-hour plasma glucose of 140–199 mg/dL (oral glucose tolerance test).

(iv) Have no previous diagnosis of Type 1 or Type 2 diabetes.

(v) Does not have end-stage renal disease (ESRD).

(2) *Medicare diabetes prevention program services*—(i) *Core sessions and core maintenance sessions.* MDPP suppliers must furnish to eligible beneficiaries the core benefit, which includes at least 16 core sessions that apply the core curriculum and 6 core maintenance sessions. All core sessions and core maintenance sessions shall have a duration of at least one hour. Sessions may be provided in-person or via remote technologies. MDPP suppliers shall address all 16 topics in the core curriculum in the core sessions and at least 6 topics in the maintenance curriculum in the core maintenance sessions.

(ii) *Ongoing maintenance sessions.* MDPP Suppliers shall furnish ongoing maintenance sessions to MDPP eligible beneficiaries who have achieved and maintained the required minimum weight loss percentage after they have completed the core maintenance sessions. All ongoing maintenance sessions shall have a duration of at least one hour. Sessions may be provided in-person or via remote technologies.

(d) *Limitations on coverage of Medicare diabetes prevention program services.* (1) The MDPP core benefit is available only once per lifetime per MDPP eligible beneficiary.

(2) The MDPP maintenance benefit is available only if the MDPP eligible beneficiary has achieved and maintains the required minimum weight loss percentage.

PART 411—EXCLUSIONS FROM MEDICARE AND LIMITATIONS ON MEDICARE PAYMENT

■ 8. The authority citation for part 411 continues to read as follows:

Authority: Secs. 1102, 1860D–1 through 1860D–42, 1871, and 1877 of the Social Security Act (42 U.S.C. 1302, 1395w–101 through 1395w–152, 1395hh, and 1395nn).

■ 9. Section 411.357 is amended by revising paragraphs (a)(5)(ii)(B), (b)(4)(ii)(B), (l)(3)(ii), and (p)(1)(ii)(B) to read as follows:

§ 411.357 Exceptions to the referral prohibition related to compensation arrangements.

* * * * *

(a) * * *

(5) * * *

(ii) * * *

(B) Per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee.

* * * * *

(b) * * *

(4) * * *

(ii) * * *

(B) Per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee.

* * * * *

(l) * * *

(3) * * *

(ii) Per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee.

* * * * *

(p) * * *

(1) * * *

(ii) * * *

(B) Per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee.

* * * * *

■ 10. Section 411.372 is amended by revising paragraph (a) to read as follows:

§ 411.372 Procedure for submitting a request.

(a) *Format for a request.* A party or parties must submit a request for an advisory opinion to CMS according to the instructions specified on the CMS Web site.

* * * * *

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

■ 11. The authority citation for part 414 continues to read as follows:

Authority: Secs. 1102, 1871, and 1881(b)(l) of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395rr(b)(l)).

■ 12. Section 414.22 is amended by revising paragraphs (b)(5) introductory text, (b)(5)(i)(A), (b)(5)(i)(B), and (b)(5)(ii) to read as follows:

§ 414.22 Relative value units (RVUs).

* * * * *

(b) * * *

(5) For services furnished in 2002 and subsequent years, the practice expense RVUs are based entirely on relative practice expense resources.

(i) * * *

(A) *Facility practice expense RVUs.* The facility practice expense RVUs apply to services furnished to patients in a hospital (except for some services furnished in a provider-based department), a skilled nursing facility, a community mental health center, a hospice, or an ambulatory surgical center, or in a wholly owned or wholly operated entity providing preadmission services under § 412.2(c)(5) of this chapter, or via telehealth under § 410.78 of the chapter.

(B) *Nonfacility practice expense RVUs.* The nonfacility practice expense RVUs apply to services furnished to patients in all locations other than those listed in paragraph (A) including, but not limited to, a physician's office, the patient's home, a nursing facility, or a comprehensive outpatient rehabilitation facility (CORF).

* * * * *

(ii) Only one practice expense RVU per code can be applied for each of the following services: Services that have only technical component practice expense RVUs or only professional component practice expense RVUs; evaluation and management services, such as hospital or nursing facility visits that are furnished exclusively in one setting; and major surgical services.

* * * * *

§ 414.32 [Removed]

■ 13. Section 414.32 is removed.

■ 14. Section 414.90 is amended by adding paragraphs (j)(1)(ii), (j)(4)(v), (j)(7)(viii) and (k)(4)(ii) to read as follows:

§ 414.90 Physician Quality Reporting System (PQRS).

* * * * *

(j) * * *

(1) * * *

(ii) Secondary Reporting Period for the 2017 PQRS payment adjustment for certain eligible professionals or group practices—Individual eligible professionals or group practices, who bill under the TIN of an ACO participant if the ACO failed to report data on behalf of such EPs or group practices during the previously established reporting period for the 2017 PQRS payment adjustment, may separately report during a secondary reporting period for the 2017 PQRS payment adjustment. The secondary reporting period for the 2017 PQRS payment adjustment for the affected individual eligible professionals or group practices is January 1, 2016 through December 31, 2016.

* * * * *

(4) * * *

(v) Paragraphs (j)(8)(ii), (iii), and (iv) of this section apply to individuals reporting using the secondary reporting period established under paragraph (j)(1)(ii) of this section for the 2017 PQRS payment adjustment.

* * * * *

(7) * * *

(viii) Paragraphs 414.90(j)(9)(ii), (iii), and (iv) of this section apply to group practices reporting using the secondary reporting period established under paragraph (j)(1)(ii) of this section for the 2017 PQRS payment adjustment.

* * * * *

(k) * * *

(4) * * *

(ii) Section 414.90(k)(5) applies to individuals and group practices reporting using the secondary reporting period established under paragraph (j)(1)(ii) of this section for the 2017 PQRS payment adjustment.

* * * * *

■ 15. Section 414.94 is amended by—

■ a. Amending paragraph (b) to add the definitions of "Applicable payment system" and "Clinical decision support mechanism" in alphabetical order.

■ b. Adding paragraphs (e)(5), (g), (h), and (i).

The additions read as follows:

§ 414.94 Appropriate use criteria for advanced diagnostic imaging services.

* * * * *

(b) * * *

Applicable payment system means the following:

(i) The physician fee schedule established under section 1848(b) of the Act;

(ii) The prospective payment system for hospital outpatient department services under section 1833(t) of the Act; and

(iii) The ambulatory surgical center payment systems under section 1833(i) of the Act.

* * * * *

Clinical decision support mechanism (CDSM) means the following: An interactive, electronic tool for use by clinicians that communicates AUC information to the user and assists them in making the most appropriate treatment decision for a patient's specific clinical condition. Tools may be modules within or available through certified EHR technology (as defined in section 1848(o)(4)) of the Act or private sector mechanisms independent from certified EHR technology or established by the Secretary.

* * * * *

(e) * * *

(5) Priority clinical areas include the following:

(i) Chest pain (including angina, suspected myocardial infarction and suspected pulmonary embolism).

(ii) Abdominal pain (any location including flank pain).

(iii) Headache (non-traumatic and traumatic).

(iv) Altered mental status.

(v) Low back pain.

(vi) Suspected stroke.

(vii) Cancer of the lung (primary or metastatic, suspected or diagnosed).

(viii) Cervical or neck pain.

* * * * *

(g) *Qualified clinical decision support mechanisms (CDSMs).* Qualified CDSMs are those specified as such by CMS. Qualified CDSMs must adhere to the requirements described in paragraph (g)(1) of this section.

(1) *Requirements for qualification of CDSMs.* A CDSM must meet all of the following requirements:

(i) Make available specified applicable AUC and the related documentation supporting the appropriateness of the applicable imaging service ordered.

(ii) Identify the appropriate use criterion consulted if the CDSM makes available more than one criterion relevant to a consultation for a patient's specific clinical scenario.

(iii) Make available, at a minimum, specified applicable AUC that reasonably encompass the entire clinical scope of all priority clinical areas identified in paragraph (e)(5) of this section.

(iv) Be able to incorporate specified applicable AUC from more than one qualified PLE.

(v) Determines, for each consultation, the extent to which the applicable imaging service is consistent with specified applicable AUC or a determination of "not applicable" when the mechanism does not contain a criterion that would apply to the consultation.

(vi) Generate and provide a certification or documentation to the ordering professional that documents which qualified CDSM was consulted; the name and national provider identifier (NPI) of the ordering professional that consulted the CDSM; and whether the service ordered would adhere to specified applicable AUC, whether the service ordered would not adhere to specified applicable AUC or whether specified applicable AUC was not applicable to the service ordered.

(A) Certification or documentation must be issued each time an ordering professional consults a qualified CDSM.

(B) Certification or documentation must include a unique consultation identifier generated by the CDSM.

(vii) Update AUC content at least every 12 months to reflect revisions or updates made by qualified PLEs to their AUC sets or an individual appropriate use criterion.

(A) A protocol must be in place to expeditiously remove AUC determined by the qualified PLE to be potentially dangerous to patients and/or harmful if followed.

(B) Specified applicable AUC that reasonably encompass the entire clinical scope of any new priority clinical area must be made available for consultation through the qualified CDSM within 12 months of the priority clinical area being finalized by CMS.

(viii) Meet privacy and security standards under applicable provisions of law.

(ix) Provide to the ordering professional aggregate feedback regarding their consultations with specified applicable AUC in the form of an electronic report on at least an annual basis.

(x) Maintain electronic storage of clinical, administrative, and demographic information of each unique consultation for a minimum of 6 years.

(xi) Comply with modification(s) to any requirements under paragraph (g)(1) of this section made through rulemaking within 12 months of the effective date of the modification.

(2) *Process to specify qualified CDSMs.* (i) The CDSM developer must submit an application to CMS for review that documents adherence to each of the CDSM requirements outlined in paragraph (g)(1) of this section;

(ii) Applications must be received by CMS annually by January 1;

(iii) All qualified CDSMs specified by CMS in each year will be included on the list of specified qualified CDSMs posted to the CMS Web site by June 30 of that year; and

(iv) Qualified CDSMs are specified by CMS as such for a period of 5 years.

(v) Qualified CDSMs are required to re-apply during the fifth year after they are specified by CMS in order to maintain their status as qualified CDSMs. This application must be received by CMS by January 1 of the 5th year after the developers' most recent approval date.

(h) *Identification of non-adherence to requirements for qualified CDSMs.* (1) If a qualified CDSM is found non-adherent to the requirements in paragraph (g)(1) of this section, CMS may terminate its qualified status or may consider this information during requalification.

(i) *Exceptions.* Consulting and reporting requirements are not required for orders for applicable imaging services made by ordering professionals under the following circumstances:

(1) Emergency services when provided to individuals with emergency medical conditions as defined in section 1867(e)(1) of the Act.

(2) For an inpatient and for which payment is made under Medicare Part A.

(3) Ordering professionals who are granted a significant hardship exception to the Medicare EHR Incentive Program payment adjustment for that year under § 495.102(d)(4) of this chapter, except for those granted such an exception under § 495.102(d)(4)(iv)(C) of this chapter.

■ 16. Section 414.1210 is amended by revising paragraphs (b)(2)(i)(B), (C), (D), and (F) to read as follows:

§ 414.1210 Application of the value-based payment modifier.

* * * * *

(b) * * *

(2) * * *

(i) * * *

(B) For groups and solo practitioners that participate in a Shared Savings Program ACO that successfully reports quality data as required by the Shared Savings Program under § 425.504, the quality composite score is calculated under § 414.1260(a) using quality data reported by the ACO for the performance period through the ACO GPRO Web interface as required under § 425.504(a)(1) of this chapter or another mechanism specified by CMS and the ACO all-cause readmission measure. Groups and solo practitioners that participate in two or more ACOs during the applicable performance period receive the quality composite score of the ACO that has the highest numerical quality composite score. For the CY 2018 payment adjustment period, the CAHPS for ACOs survey also will be included in the quality composite score. For the CY 2017 and 2018 payment adjustment periods, for groups and solo practitioners who participate in a Shared Savings Program ACO that does not successfully report quality data as required by the Shared Savings Program under § 425.504 and who meet the requirements to avoid the PQRS payment adjustment for CY 2018 by reporting to the PQRS outside the ACO, the quality composite is classified as "average" under § 414.1275(b).

(C) For the CY 2017 payment adjustment period, the value-based payment modifier adjustment will be equal to the amount determined under § 414.1275 for the payment adjustment period, except that if the ACO (or groups and solo practitioners that participate in the ACO) does not successfully report quality data as described in paragraph (b)(2)(i)(B) of this section for the performance period, such adjustment will be equal to −4% for groups of physicians with 10 or more eligible professionals and equal to −2% for groups of physicians with two to nine eligible professionals and for physician solo practitioners. If the ACO has an assigned beneficiary population during the performance period with an average risk score in the top 25 percent of the risk scores of beneficiaries nationwide, and a group of physician or physician solo practitioner that participates in the ACO during the performance period is classified as high quality/average cost under quality-tiering for the CY 2017 payment adjustment period, the group or solo practitioner receives an upward adjustment of +3 × (rather than +2 ×) if the group has 10 or more eligible professionals or +2 × (rather than +1 ×) for a solo practitioner or the group has two to nine eligible professionals.

(D) For the CY 2018 payment adjustment period, the value-based payment modifier adjustment will be equal to the amount determined under § 414.1275 for the payment adjustment period, except that if the ACO (or groups and solo practitioners that participate in the ACO) does not successfully report quality data as described in paragraph (b)(2)(i)(B) of this section for the performance period, such adjustment will be equal to the downward payment adjustment amounts described at § 414.1270(d)(1). If the ACO has an assigned beneficiary population during the performance period with an average risk score in the top 25 percent of the risk scores of beneficiaries nationwide, and a group or solo practitioner that participates in the ACO during the performance period is classified as high quality/average cost under quality-tiering for the CY 2018 payment adjustment period, the group or solo practitioner receives an upward adjustment of +3 × (rather than +2 ×) if the group of physicians has 10 or more eligible professionals, +2 × (rather than +1 ×) for a physician solo practitioner or if the group of physicians has two to nine eligible professionals, or +2 × (rather than +1 ×) for a solo practitioner who is a nonphysician eligible professional or if the group consists of nonphysician eligible professionals.

* * * * *

(F) For groups and solo practitioners that participate in a Shared Savings Program ACO that successfully reports quality data as required by the Shared Savings Program under § 425.504 of this chapter, the same value-based payment modifier adjustment will be applied in the payment adjustment period to all groups based on size as specified under § 414.1275 and solo practitioners that participated in the ACO during the performance period.

* * * * *

PART 417—HEALTH MAINTENANCE ORGANIZATIONS, COMPETITIVE MEDICAL PLANS, AND HEALTH CARE PREPAYMENT PLANS

■ 17. The authority citation for part 417 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh), secs. 1301, 1306, and 1310 of the Public Health Service Act (42 U.S.C. 300e, 300e–5, and 300e–9), and 31 U.S.C. 9701.

■ 18. Section 417.478 is amended by adding paragraph (e) to read as follows:

§ 417.478 Requirements of other laws and regulations.

* * * * *

(e) Sections 422.222 and 422.224 of this chapter which requires all providers or suppliers, as defined in section 1861 of the Act, to be enrolled in Medicare in an approved status and prohibits payment to providers and suppliers that are excluded or revoked.

■ 19. Section 417.484 is amended by adding paragraph (b)(3) to read as follows:

§ 417.484 Requirement applicable to related entities.

(b) * * *

(3) All providers and suppliers, as defined in section 1861 of the Act, are enrolled in Medicare in an approved status.

PART 422—MEDICARE ADVANTAGE PROGRAM

■ 20. The authority citation for part 422 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 21. Section 422.1 is amended by redesignating paragraphs (a)(1)(i) through (x) as paragraphs (a)(1)(ii) through (xi) and adding new paragraph (a)(1)(i) to read as follows:

§ 422.1 Basis and scope.

(a) * * *

(1) * * *

(i) 1106—Disclosure of information in possession of agency.

* * * * *

■ 22. Section 422.204 is amended by adding paragraph (b)(5) to read as follows:

§ 422.204 Provider selection and credentialing.

* * * * *

(b) * * *

(5) Ensures compliance with the provider and supplier enrollment requirements at § 422.222.

■ 23. Section 422.222 is added to subpart E to read as follows:

§ 422.222 Enrollment of MA organization network providers and suppliers; first-tier, downstream, and related entities (FDRs); and providers and suppliers in Program of All-inclusive Care for the Elderly (PACE) plans, cost HMO or CMP, and demonstration and pilot programs.

(a) Providers or suppliers that are types of individuals or entities that can enroll in Medicare in accordance with section 1861 of the Act, must be enrolled in Medicare and be in an approved status in Medicare in order to provide health care items or services to a Medicare enrollee who receives his or her Medicare benefit through an MA organization. This requirement applies to all of the following providers and suppliers:

(1) Network providers and suppliers.

(2) First-tier, downstream, and related entities (FDR).

(3) Providers and suppliers in Program of All-inclusive Care for the Elderly (PACE) plans.

(4) Providers and suppliers in Cost HMOs or CMPs, as defined in 42 CFR part 417.

(5) Providers and suppliers participating in demonstration programs.

(6) Providers and suppliers in pilot programs.

(7) Locum tenens suppliers.

(8) Incident-to suppliers.

(b) MA organizations that do not ensure that providers and suppliers comply with paragraph (a) of this section, may be subject to sanctions under § 422.750 and termination under § 422.510.

■ 24. Section 422.224 is added to subpart E to read as follows:

§ 422.224 Payment to providers or suppliers excluded or revoked.

(a) An MA organization may not pay, directly or indirectly, on any basis, for items or services (other than emergency or urgently needed services as defined in § 422.2) furnished to a Medicare enrollee by any individual or entity that is excluded by the Office of the Inspector General (OIG) or is revoked from the Medicare program except as provided in paragraph (b) of this section.

(b) If an MA organization receives a request for payment by, or on behalf of, an individual or entity that is excluded by the OIG or is revoked in the Medicare program, the MA organization must notify the enrollee and the excluded or revoked individual or entity in writing, as directed by contract or other direction provided by CMS, that future payments must not be made. Payment may not be made to, or on behalf of, an individual or entity after the first payment is made or as permitted in-writing by CMS.

■ 25. Section 422.250 is revised to read as follows:

§ 422.250 Basis and scope.

This subpart is based largely on section 1854 of the Act, but also includes provisions from sections 1853 and 1858 of the Act, and is also based on section 1106 of the Act. It sets forth the requirements for the Medicare Advantage bidding payment methodology, including CMS' calculation of benchmarks, submission of plan bids by Medicare Advantage (MA) organizations, establishment of beneficiary premiums and rebates through comparison of plan bids and benchmarks, negotiation and approval of bids by CMS, and the release of MA bid submission data.

■ 26. Section 422.272 is added to subpart F to read as follows:

§ 422.272 Release of MA bid pricing data.

(a) *Terminology.* For purposes of this section, the term "MA bid pricing data" means the following information that MA organizations must submit for each MA plan bid for the annual bid submission:

(1) The pricing-related information described at § 422.254(a)(1); and

(2) The information required for MSA plans, described at § 422.254(e).

(b) *Release of MA bid pricing data.* Subject to paragraph (c) of this section and to the annual timing identified in paragraph (d) of this section, CMS will release to the public MA bid pricing data for MA plan bids accepted or approved by CMS for a contract year under § 422.256. The annual release will contain MA bid pricing data from the final list of MA plan bids accepted or approved by CMS for a contract year that is at least 5 years prior to the upcoming calendar year.

(c) *Exclusions from release of MA bid pricing data.* For the purpose of this section, the following information is excluded from the data released under paragraph (b) of this section:

(1) For an MA plan bid that includes Part D benefits, the information described at § 422.254(b)(1)(ii), (c)(3)(ii), and (c)(7);

(2) Additional information that CMS requires to verify the actuarial bases of the bids for MA plans for the annual bid submission as follows:

(i) Narrative information on base period factors, manual rates, cost-sharing methodology, optional supplement benefits, and other required narratives; and

(ii) Supporting documentation.

(3) Any information that could be used to identify Medicare beneficiaries and other individuals.

(4) Bid review correspondence and reports.

(d) *Timing of data release.* CMS will release MA bid pricing data as provided in paragraph (b) of this section on an annual basis after the first Monday in October.

■ 27. Section 422.501 is amended by adding paragraph (c)(1)(iv) and revising paragraph (c)(2) to read as follows:

§ 422.501 Application requirements.

* * * * *

(c) * * *

(1) * * *

(iv) Documentation that all providers and suppliers in the MA or MA–PD plan who can enroll in Medicare, are enrolled in an approved status.

(2) The authorized individual must thoroughly describe how the entity and MA plan meet, or will meet, all the requirements described in this part, including providing documentation that all providers and suppliers referenced in § 422.222 are enrolled in Medicare in an approved status.

* * * * *

■ 28. Section 422.504 is amended by—

■ A. Revising paragraph (a)(6).

■ B. Adding paragraph (i)(2)(v).

■ C. Revising paragraph (n).

The revisions and addition read as follows:

§ 422.504 Contract provisions.

* * * * *

(a) * * *

(6) To comply with all applicable provider and supplier requirements in subpart E of this part, including provider certification requirements, anti-discrimination requirements, provider participation and consultation requirements, the prohibition on interference with provider advice, limits on provider indemnification, rules governing payments to providers, limits on physician incentive plans, and Medicare provider and supplier enrollment requirements.

* * * * *

(i) * * *

(2) * * *

(v) They will require all of their providers and suppliers to be enrolled in Medicare in an approved status consistent with § 422.222.

* * * * *

(n) *Acknowledgements of CMS release of data*—(1) *Summary CMS payment data.* The contract must provide that the MA organization acknowledges that CMS releases to the public summary reconciled CMS payment data after the reconciliation of Part C and Part D payments for the contract year as follows:

(i) For Part C, the following data—

(A) Average per member per month CMS payment amount for A/B (original Medicare) benefits for each MA plan offered, standardized to the 1.0 (average risk score) beneficiary.

(B) Average per member per month CMS rebate payment amount for each MA plan offered (or, in the case of MSA plans, the monthly MSA deposit amount).

(C) Average Part C risk score for each MA plan offered.

(D) County level average per member per month CMS payment amount for each plan type in that county, weighted by enrollment and standardized to the 1.0 (average risk score) beneficiary in that county.

(ii) For Part D plan sponsors, plan payment data in accordance with § 423.505(o) of this subchapter.

(2) *MA bid pricing data and Part C MLR data.* The contract must provide that the MA organization acknowledges that CMS releases to the public data as described at §§ 422.272 and 422.2490.

* * * * *

■ 29. Section 422.510 is amended by adding paragraph (a)(4)(xiii) to read as follows:

§ 422.510 Termination of contract by CMS.

(a) * * *

(4) * * *

(xiii) Fails to meet provider and supplier enrollment requirements in accordance with §§ 422.222 and 422.224.

* * * * *

■ 30. Section 422.752 is amended by adding paragraph (a)(13) to read as follows:

§ 422.752 Basis for imposing intermediate sanctions and civil money penalties.

(a) * * *

(13) Fails to comply with §§ 422.222 and 422.224, that requires the MA organization to ensure providers and suppliers are enrolled in Medicare and not make payment to excluded or revoked individuals or entities.

* * * * *

■ 31. Section 422.2400 is revised to read as follows:

§ 422.2400 Basis and scope.

This subpart is based on sections 1857(e)(4), 1860D–12(b)(3)(D), and 1106 of the Act, and sets forth medical loss ratio requirements for Medicare Advantage organizations, financial penalties and sanctions against MA organizations when minimum medical loss ratios are not achieved by MA organizations, and release of medical loss ratio data to entities outside of CMS.

■ 32. Section 422.2490 is added to subpart X to read as follows:

§ 422.2490 Release of Part C MLR data.

(a) *Terminology.* Subject to the exclusions in paragraph (b) of this section, Part C MLR data consists of the information contained in reports submitted under § 422.2460.

(b) *Exclusions from Part C MLR data.* For the purpose of this section, the following items are excluded from Part C MLR data:

(1) Narrative descriptions that MA organizations submit to support the information reported to CMS pursuant to the reporting requirements at § 422.2460, such as descriptions of expense allocation methods;

(2) Information that is reported at the plan level, such as the number of member months associated with each plan under a contract;

(3) Any information that could be used to identify Medicare beneficiaries and other individuals; and

(4) MLR review correspondence.

(c) *Data release.* CMS releases to the public Part C MLR data, for each contract for each contract year, no earlier than 18 months after the end of the applicable contract year.

PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

■ 33. The authority citation for part 423 continues to read as follows:

Authority: Sections 1102, 1106, 1860D–1 through 1860D–42, and 1871 of the Social Security Act (42 U.S.C. 1302, 1306, 1395w–101 through 1395w–152, and 1395hh).

■ 34. Section 423.505 is amended by revising paragraph (o) to read as follows:

§ 423.505 Contract provisions.

* * * * *

(o) *Acknowledgements of CMS release of data*—(1) *Summary CMS payment data.* The contract must provide that the Part D sponsor acknowledges that CMS releases to the public summary reconciled Part D payment data after the reconciliation of Part D payments for the contract year as follows:

(i) The average per member per month Part D direct subsidy standardized to the 1.0 (average risk score) beneficiary for each Part D plan offered.

(ii) The average Part D risk score for each Part D plan offered.

(iii) The average per member per month Part D plan low-income cost sharing subsidy for each Part D plan offered.

(iv) The average per member per month Part D Federal reinsurance subsidy for each Part D plan offered.

(v) The actual Part D reconciliation payment data summarized at the Parent Organization level including breakouts of risk sharing, reinsurance, and low income cost sharing reconciliation amounts.

(2) *Part D MLR data.* The contract must provide that the Part D sponsor acknowledges that CMS releases to the public data as described at § 423.2490.

* * * * *

■ 35. Section 423.2400 is revised to read as follows:

§ 423.2400 Basis and scope.

This subpart is based on sections 1857(e)(4), 1860D–12(b)(3)(D), and 1106 of the Act, and sets forth medical loss ratio requirements for Part D sponsors, financial penalties and sanctions against Part D sponsors when minimum medical loss ratios are not achieved by Part D sponsors and release of medical loss ratio data to entities outside of CMS.

■ 36. Section 423.2490 is added to subpart X to read as follows:

§ 423.2490 Release of Part D MLR data.

(a) *Terminology.* Subject to the exclusions in paragraph (b) of this section, Part D MLR data consists of the information contained in reports submitted under § 423.2460.

(b) *Exclusions from Part D MLR data.* For the purpose of this section, the following items are excluded from Part D MLR data:

(1) Narrative descriptions that Part D sponsors submit to support the information reported to CMS pursuant to the reporting requirements at § 423.2460, such as descriptions of expense allocation methods;

(2) Information that is reported at the plan level, such as the number of member months associated with each plan under a contract;

(3) Any information that could be used to identify Medicare beneficiaries and other individuals; and

(4) MLR review correspondence.

(c) *Data release.* CMS releases to the public Part D MLR data, for each contract for each contract year, no earlier than 18 months after the end of the applicable contract year.

PART 424—CONDITIONS FOR MEDICARE PAYMENT

■ 37. The authority citation for part 424 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 38. Section 424.59 is added to subpart D to read as follows:

§ 424.59 Payment to organizations that provide Medicare Diabetes Prevention Program Services.

(a) *Conditions for enrollment.* An entity that is not already enrolled in Medicare on the basis of being an existing Medicare provider or supplier may enroll as an MDPP supplier if it satisfies the following criteria:

(1) Has Full DPRP recognition, or has preliminary DPRP recognition and progresses to full DPRP recognition within 36 months of the date upon which it applied for DPRP recognition.

(2) Has obtained and maintains an active and valid TIN and NPI at the organizational level.

(3) Has passed application screening at a high categorical risk level per § 424.518(c).

(4) All coaches who will be furnishing MDPP services on the entity's behalf have obtained and maintain active and valid NPIs.

(b) *Conditions for existing Medicare providers or suppliers.* An existing Medicare provider or supplier that wishes to bill for MDPP would not have to submit a separate enrollment application but must satisfy the following criteria:

(1) Has Full DPRP recognition, or has preliminary DPRP recognition and progresses to full DPRP recognition within 36 months of the date upon which it applied for DPRP recognition.

(2) All coaches who will be furnishing MDPP services on the entity's behalf have obtained and maintain active and valid NPIs.

(c) *Conditions for payment of claims for MDPP services provided.* An MDPP supplier must meet all of the following requirements in order to receive payment for claims made for MDPP Services provided:

(1) Establishes and maintains a recordkeeping system that is adequate to document and monitor beneficiaries' session attendance and weight at every MDPP session. MDPP suppliers are required to maintain and handle any beneficiary PII and PHI in compliance with HIPAA, other applicable privacy laws and CMS standards.

(2) Maintains a crosswalk between the beneficiary identifiers submitted to CMS for billing and the beneficiary identifiers submitted to CDC for beneficiary level-clinical data.

(3) Attests that the MDPP eligible beneficiary for which it is submitting a claim has attended 1, 4 or 9 core sessions, and, if applicable, achieved the required minimum weight loss percentage specified in § 410.79 of this chapter.

(4) If applicable, attests that the MDPP eligible beneficiary for which it is submitting a claim has maintained the required minimum weight loss percentage and attended core maintenance sessions.

(5) If applicable, attests that the MDPP eligible beneficiary for which it is submitting a claim has maintained the required minimum weight loss percentage and attended ongoing maintenance sessions.

(6) Submits any documentation requested by CMS or a Medicare contractor to substantiate the attestations described in this section or claims submitted for payment under the Medicare program.

(7) Submits any documentation requested by CMS or a Medicare contractor to support supplier or coach enrollment in Medicare.

(8) Complies with the requirements of subpart P of this part.

(9) Retains beneficiary records for 7 years from the date of service, and upon request of CMS or a Medicare contractor provides access to such records.

(i) The records must contain detailed documentation of the services provided including the beneficiary's eligibility status, sessions attended, the coach furnishing the session attended, the date and place of service of sessions attended, and weight.

(ii) The records shall be maintained within a larger medical record, or within a medical record that an MDPP supplier establishes for the purposes administering MDPP.

(d) *Loss of MDPP billing privileges.* An MDPP supplier is subject to revocation of Medicare billing privileges for MDPP services if any of the following occur:

(1) Fails to move from Preliminary to Full Recognition within 36 months of applying for DPRP recognition.

(2) Loses its DPRP recognition or withdraws from seeking DPRP recognition.

(3) Medicare suppliers that lose DPRP recognition will lose Medicare billing privileges for MDPP services, but may continue to bill for non-MDPP services for which they remain eligible to bill.

(e) *Restoration of MDPP billing privileges; appeal rights.* An MDPP supplier that has lost its MDPP billing privileges may:

(1) Become eligible to bill for MDPP services again if it reapplies for DPRP recognition, successfully achieves preliminary DPRP recognition, and, as applicable, reenrolls in Medicare as an MDPP supplier subject to § 424.59(a).

(2) Appeal in accordance with the procedures specified in 42 CFR part 405, subpart H, 42 CFR part 424, and 42 CFR part 498.

PART 425—MEDICARE SHARED SAVINGS PROGRAM

■ 39. Authority: Secs. 1102, 1106, 1871, and 1899 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 40. Section 425.110 is amended by revising paragraph (b)(1) to read as follows:

§ 425.110 Number of ACO professionals and beneficiaries.

* * * * *

(b) * * *

(1) While under the CAP, the ACO remains eligible for shared savings and losses.

(i) For ACOs with a variable MSR and MLR (if applicable), the MSR and MLR (if applicable) will be set at a level consistent with the number of assigned beneficiaries.

(ii) For ACOs with a fixed MSR/MLR, the MSR/MLR will remain fixed at the level consistent with the ACO's choice of MSR and MLR that the ACO made at the start of the agreement period.

* * * * *

§ 425.204 [Amended]

■ 41. § 425.204 is amended by—

■ a. Amending paragraph (g) heading to remove the phrase "and acquired Medicare-enrolled TINs" and adding in its place the phrase "and acquired entities' TINs".

■ b. Amending paragraph (g) introductory text to remove the phrase "claims billed by Medicare-enrolled entities' TINs that" and adding in its place the phrase "claims billed under the TINs of entities that".

■ c. Amending paragraph (g)(1) introductory text to remove the phrase "an acquired Medicare-enrolled entity's TIN" and adding in its place the phrase "an acquired entity's TIN".

■ d. Amending paragraph (g)(1)(i) to remove the phrase "the acquired entity's Medicare-enrolled TIN" and adding in its place the phrase "the acquired entity's TIN"

■ e. Amending paragraph (g)(2)(i)(A) to remove the phrase "Identifies by Medicare-enrolled TIN" and adding in its place the phrase "Identifies by TIN".

§ 425.316 [Amended]

■ 42. Amend 425.316—

■ a. In paragraph (c)(1), by removing the phrase "minimum attainment level in one or more domains as determined under § 425.502 and may be subject to a CAP. CMS, may forgo the issuance" and adding in its place the phrase "minimum attainment level on at least 70 percent of the measures, as determined under § 425.502, in one or more domains and may be subject to a CAP. CMS may forgo the issuance".

■ b. In paragraph (c)(2) by removing the phrase "quality performance standards" and adding in its place the phrase "quality performance standard".

■ 43. Section 425.402 is amended by adding paragraph (e) to read as follows:

§ 425.402 Basic assignment methodology.

* * * * *

(e) Beginning in performance year 2018, CMS will supplement the claims-based assignment methodology described in this section with information provided by beneficiaries regarding the provider or supplier they consider responsible for coordinating their overall care. If a system is available by spring 2017 to allow a beneficiary to designate a provider or supplier as responsible for coordinating their overall care and CMS to process the designation electronically, then the voluntary alignment process under paragraph (e) will be available for ACOs participating in Track 1, Track 2, or Track 3, as specified in § 425.600(a). If such an electronic system is not available by spring 2017, CMS will specify the form and manner in which a beneficiary may designate a provider or supplier as responsible for coordinating their overall care using a manual process, but the voluntary alignment process will be limited to ACOs participating in Track 3 until an electronic system is available.

(1) Notwithstanding the assignment methodology under paragraph (b) of this section, beneficiaries who designate an ACO professional participating in an ACO as responsible for coordinating their overall care will be added to the ACO's list of assigned beneficiaries for a performance year under all of the following conditions:

(i) The beneficiary must have had at least one primary care service with a physician who is an ACO professional in the ACO and who is a primary care physician as defined under § 425.20 or who has one of the primary specialty designations included in paragraph (c) of this section.

(ii) The beneficiary meets the eligibility criteria established at § 425.401(a) and must not be excluded by the criteria at § 425.401(b).

(iii) The beneficiary must have designated an ACO professional who is a primary care physician as defined at § 425.20, a physician with a specialty designation included at paragraph (c) of this section, or a nurse practitioner, physician assistant, or clinical nurse specialist as responsible for their overall care.

(iv) If a beneficiary has designated a provider or supplier outside the ACO who is a primary care physician as defined at § 425.20, a physician with a specialty designation included at paragraph (c) of this section, or a nurse practitioner, physician assistant, or clinical nurse specialist, as responsible for coordinating their overall care, the beneficiary will not be added to the ACO's list of assigned beneficiaries for a performance year under the assignment methodology in paragraph (b).

(2) The ACO, ACO participants, ACO providers/suppliers, ACO professionals, and other individuals or entities performing functions and services related to ACO activities are prohibited from providing or offering gifts or other remuneration to Medicare beneficiaries as inducements for influencing a Medicare beneficiary's decision to designate or not to designate an ACO professional under paragraph (e) of this section. The ACO, ACO participants, ACO providers/suppliers, ACO professionals, and other individuals or entities performing functions and services related to ACO activities must not, directly or indirectly, commit any

act or omission, nor adopt any policy that coerces or otherwise influences a Medicare beneficiary's decision to designate or not to designate an ACO professional as responsible for coordinating their overall care under paragraph (e) of this section, including but not limited to the following:

(i) Offering anything of value to the Medicare beneficiary as an inducement for influencing the Medicare beneficiary's decision to designate or not to designate an ACO professional as responsible for coordinating their overall care under paragraph (e) of this section. Any items or services provided in violation of paragraph (e)(3) will not be considered to have a reasonable connection to the medical care of the beneficiary, as required under § 425.304(a)(2);

(ii) Withholding or threatening to withhold medical services or limiting or threatening to limit access to care.

(iii) If a manual process is implemented by CMS, including any voluntary alignment form that requires a beneficiary signature with any other materials or forms, including but not limited to, any other materials requiring the signature of the Medicare beneficiary.

■ 44. Section 425.500 is amended by revising paragraphs (e)(2) and (3) to read as follows:

§ 425.500 Measures to assess the quality of care furnished by an ACO.

* * * * *

(e) * * *

(2) If, at the conclusion of the audit process the overall audit match rate between the quality data reported and the medical records provided under paragraph (e)(1) of this section is less than 90 percent, CMS will adjust the ACO's overall quality score proportional to the ACO's audit performance.

(3) If, at the conclusion of the audit process CMS determines there is an audit match rate of less than 90 percent, the ACO may be required to submit a CAP under § 425.216 for CMS approval.

* * * * *

■ 45. Section 425.502 is amended by—

■ a. Revising paragraph (a) introductory text.

■ b. In paragraph (a)(1), removing the phrase "period, CMS, CMS defines" and adding in its place the phrase "period, CMS defines"

■ c. In paragraphs (a)(2) and (a)(3), removing the phrase "level of certain measures" and adding in its place "level of all measures"

■ d. In paragraph (a)(4), removing the phrases "The quality performance standard for a newly" and "periods, the quality performance standard for the measure" and adding in its place the phrases "A newly" and "periods, the measure", respectively.

■ e. In paragraph (b)(2)(ii), removing the phrase "95 percentt" and adding in its place the phrase "95 percent".

■ f. Revising paragraph (b)(3).

■ g. In paragraph (c)(2), removing the phrase "level for a measure" and adding in its place the phrase "level for a pay-for-performance measures".

■ h. Adding paragraph (c)(5).

■ i. In paragraph (d), removing the phrase "quality performance requirements" each time it appears and adding in its place the phrase "quality requirements".

■ j. In paragraph (d)(1) introductory text, removing the phrase "individual quality performance standard measures" and adding in its place the phrase "individual measures".

■ k. Revising paragraph (d)(2)(ii).

The revisions and addition read as follows:

§ 425.502 Calculating the ACO quality performance score.

(a) *Establishing a quality performance standard.* CMS designates the quality performance standard in each performance year. The quality performance standard is the overall standard the ACO must meet in order to be eligible for shared savings.

* * * * *

(b) * * *

(3) The minimum attainment level for pay for performance measures is set at 30 percent or the 30th percentile of the performance benchmark. The minimum attainment level for pay for reporting measures is set at the level of complete and accurate reporting.

* * * * *

(c) * * *

(5) Performance equal to or greater than the minimum attainment level for pay-for-reporting measures will receive the maximum available points.

* * * * *

(d) * * *

(2) * * *

(ii) CMS may take the compliance actions described in § 425.216 for ACOs exhibiting poor performance on a domain, as determined by CMS under § 425.316.

■ 46. Section 425.504 is amended by—

■ a. Amending paragraph (c) to remove the phrase "for 2016 and subsequent years" everywhere it appears and adding in its place the phrase "for 2016".

■ b. Redesignating paragraph (d) as paragraph (c)(5).

■ c. Adding new paragraph (d).

The addition reads as follows:

§ 425.504 Incorporating reporting requirements related to the Physician Quality Reporting System Incentive and Payment Adjustment.

* * * * *

(d) *Physician Quality Reporting System payment adjustment for 2017 and 2018.* (1) ACOs, on behalf of eligible professionals who bill under the TIN of an ACO participant, must submit all of the ACO GPRO measures determined under § 425.500 using a CMS web interface, to satisfactorily report on behalf of their eligible professionals for purposes of the Physician Quality Reporting System payment adjustment under the Shared Savings Program for 2017 and 2018.

(2) Eligible professionals who bill under the TIN of an ACO participant within an ACO participate under their ACO participant TIN as a group practice under the Physician Quality Reporting System Group Practice Reporting Option of the Shared Savings Program for purposes of the Physician Quality Reporting System payment adjustment under the Shared Savings Program for 2017 and 2018.

(3) If an ACO, on behalf of eligible professionals who bill under the TIN of an ACO participant, does not satisfactorily report for purposes of the Physician Quality Reporting System payment adjustment for 2017 or 2018, each eligible professional who bills under the TIN of an ACO participant will receive a payment adjustment, as described in § 414.90(e) of this chapter, unless such eligible professionals have reported quality measures apart from the ACO in the form and manner required by the Physician Quality Reporting System.

(4) For eligible professionals subject to the Physician Quality Reporting System payment adjustment under the Medicare Shared Savings Program for 2017 or 2018, the Medicare Part B Physician Fee Schedule amount for covered professional services furnished during the program year is equal to the applicable percent of the Medicare Part B Physician Fee Schedule amount that would otherwise apply to such services under section 1848 of the Act, as described in § 414.90(e) of this chapter.

(5) The reporting period for a year is the calendar year from January 1 through December 31 that occurs 2 years prior to the program year in which the payment adjustment is applied, unless otherwise specified by CMS under the Physician Quality Reporting System.

■ 47. Section 425.506 is amended by—

■ a. Revising the section heading.

■ b. Amending paragraph (d) to remove the phrase "Eligible professionals participating in an ACO" and adding in its place the phrase "Through reporting period 2016, eligible professionals participating in an ACO"

■ c. Adding paragraph (e).

The revision and addition read as follows:

§ 425.506 Incorporating reporting requirements related to adoption of certified electronic health record technology.

* * * * *

(e) For 2017 and subsequent years, CMS will annually assess the degree of use of certified EHR technology by eligible clinicians billing through the TINs of ACO participants for purposes of meeting the CEHRT criterion necessary for Advanced Alternative Payment Models under the Quality Payment Program.

(1) During years in which the measure is designated as pay for reporting, in order to demonstrate complete and accurate reporting, at least one eligible clinician billing through the TIN of an ACO participant must meet the reporting requirements under the Advancing Clinical Information category under the Quality Payment Program.

(2) During years in which the measure is designated as pay for performance, the quality measure regarding EHR adoption will be measured based on a sliding scale.

■ 48. Section 425.508 is added to subpart F to read as follows:

§ 425.508 Incorporating quality reporting requirements related to the Quality Payment Program.

(a) *For 2017 and subsequent reporting years.* ACOs, on behalf of eligible clinicians who bill under the TIN of an ACO participant, must submit all of the CMS web interface measures determined under § 425.500 to satisfactorily report on behalf of their eligible clinicians for purposes of the quality performance category of the Quality Payment Program.

(b) [Reserved]

■ 49. Section 425.612 is amended by—

■ a. Amending paragraph (a)(1) introductory text to remove the phrase "ACOs participating in Track 3 that receive otherwise" and adding in its place the phrase "ACOs participating in Track 3, and as provided in paragraph (a)(1)(iv) of this section during a grace period for beneficiaries excluded from prospective assignment to a Track 3 ACO, who receive otherwise".

■ b. Adding paragraphs (a)(1)(iv), (a)(1)(v), and (d)(4).

The additions read as follows:

§ 425.612 Waivers of payment rules or other Medicare requirements.

(a) * * *

(1) * * *

(iv) For a beneficiary who was included on the prospective assignment list under § 425.400(a)(3) for a performance year for a Track 3 ACO for which a waiver of the SNF 3-day rule has been approved under paragraph (a)(1) of this section, but who was subsequently excluded from the ACO's prospective assignment list, CMS makes payment for SNF services furnished to the beneficiary by a SNF affiliate if the following conditions are met:

(A) The beneficiary was prospectively assigned to the ACO at the beginning of the applicable performance year but was excluded in the most recent quarterly update to the prospective assignment list under § 425.401(b).

(B) The SNF services are furnished to a beneficiary who was admitted to a SNF affiliate within 90 days following the date that CMS delivers the quarterly exclusion list to the ACO.

(C) But for the beneficiary's exclusion from the ACO's prospective assignment list, CMS would have made payment to the SNF affiliate for such services under the waiver under paragraph (a)(1) of this section.

(v) The following beneficiary protections apply when a beneficiary receives SNF services without a prior 3-day inpatient hospital stay from a SNF affiliate that intended to provide services pursuant to a SNF 3-day rule waiver under paragraph (a)(1) of this section, but the beneficiary was not prospectively assigned to the ACO and was not in the 90 day grace period under paragraph (a)(1)(iv) of this section. The SNF affiliate services must be non-covered only because the SNF affiliate stay was not preceded by a qualifying hospital stay under section 1861(i) of the Act.

(A) A SNF is presumed to intend to provide services pursuant to the SNF 3-day rule waiver under paragraph (a)(1) of this section if the SNF submitting the claim is a SNF affiliate of an ACO for which such a waiver has been approved.

(B) CMS makes no payments for SNF services to a SNF affiliate of an ACO for which a waiver of the SNF 3-day rule has been approved when the SNF affiliate admits a FFS beneficiary who was never prospectively assigned to the ACO or was prospectively assigned but was later excluded and the 90 day grace period under paragraph (a)(1)(iv) of this section has lapsed.

(C) In the event that CMS makes no payment for SNF services furnished by a SNF affiliate as a result of paragraph (a)(1)(v)(B) of this section and the only reason the claim was non-covered is due to the lack of a qualifying inpatient stay, the following beneficiary protections will apply:

(1) The SNF must not charge the beneficiary for the expenses incurred for such services; and

(2) The SNF must return to the beneficiary any monies collected for such services; and

(3) The ACO may be required to submit a corrective action plan under § 425.216(b) for CMS approval. If after being given an opportunity to act upon the corrective action plan the ACO fails to come into compliance with the requirements of paragraph (a)(1), approval for the SNF 3-day rule waiver under this section will be terminated as provided under paragraph (d) of this section.

* * * * *

(d) * * *

(4) CMS reserves the right to take compliance action, including termination, against an ACO for noncompliance with program rules, including misuse of a waiver under this section, as specified at §§ 425.216 and 425.218.

* * * * *

PART 460—PROGRAMS OF ALL-INCLUSIVE CARE FOR THE ELDERLY (PACE)

■ 50. The authority citation for part 460 continues to read as follows:

Authority: Secs. 1102, 1871, 1894(f), and 1934(f) of the Social Security Act (42 U.S.C. 1302, 1395, 1395eee(f), and 1396u–4(f)).

■ 51. Section 460.32 is amended by adding paragraph (a)(14) to read as follows:

§ 460.32 Content and terms of PACE program agreement.

(a) * * *

(14) Name and National Provider Identifier (NPI) of all providers and suppliers, as defined in 1861 of the Act, reflecting enrollment in Medicare in an approved status.

* * * * *

■ 52. Section 460.40 is amended by adding paragraph (j) to read as follows:

§ 460.40 Violations for which CMS may impose sanctions.

* * * * *

(j) Employs or contracts with any provider or supplier, as defined in section 1861 of the Act, that is not enrolled in Medicare in an approved status.

■ 53. Section 460.50 is amended by revising paragraph (b)(1)(ii) to read as follows:

§ 460.50 Termination of PACE program agreement.

(b) * * *

(1) * * *

(ii) The PACE organization failed to comply substantially with conditions for a PACE program or PACE organization under this part, or with terms of its PACE program agreement, including employing or contracting with any provider or supplier, as defined in section 1861 of the Act, that is not enrolled in Medicare in an approved status.

* * * * *

■ 54. Section 460.68 is amended by adding paragraph (a)(4) to read as follows:

§ 460.68 Program integrity.

(a) * * *

(4) That are not enrolled in Medicare in an approved status, if they are a provider or supplier that is eligible to enroll in Medicare, as defined in section 1861 of the Act.

* * * * *

■ 55. Section 460.70 is amended by revising paragraph (b)(1)(ii) to read as follows:

§ 460.70 Contracted services.

* * * * *

(b) * * *

(1) * * *

(ii) A practitioner or supplier must meet Medicare or Medicaid requirements applicable to the services it furnishes, including enrollment in Medicare in an approved status, if they are a provider or supplier that is eligible to enroll in Medicare, as defined in section 1861 of the Act.

* * * * *

Dated: June 2, 2016.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

Dated: June 23, 2016.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

[FR Doc. 2016–16097 Filed 7–7–16; 4:15 pm]

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Part III

Department of the Interior

Bureau of Ocean Energy Management

30 CFR Parts 250, 254, and 550
Oil and Gas and Sulfur Operations on the Outer Continental Shelf—Requirements for Exploratory Drilling on the Arctic Outer Continental Shelf; Final Rule

DEPARTMENT OF THE INTERIOR

Bureau of Safety and Environmental Enforcement

30 CFR Parts 250, 254, and 550

Bureau of Ocean Energy Management

30 CFR Part 550

[Docket ID: BSEE–2013–0011; 16XE1700DX EX1SF0000.DAQ000 EEEE500000]

RIN 1082–AA00

Oil and Gas and Sulfur Operations on the Outer Continental Shelf—Requirements for Exploratory Drilling on the Arctic Outer Continental Shelf

AGENCY: Bureau of Safety and Environmental Enforcement (BSEE); Bureau of Ocean Energy Management (BOEM), Interior.

ACTION: Final rule.

SUMMARY: The Department of the Interior (DOI or the Department), acting through BOEM and BSEE, is revising and adding new requirements to regulations for exploratory drilling and related operations on the Outer Continental Shelf (OCS) seaward of the State of Alaska. This final rule focuses solely on the OCS within the Beaufort Sea and Chukchi Sea Planning Areas (Arctic OCS). The Arctic region is characterized by extreme environmental conditions, geographic remoteness, and a relative lack of fixed infrastructure and existing operations. This final rule is designed to help ensure the safe, effective, and responsible exploration of Arctic OCS oil and gas resources, while protecting the marine, coastal, and human environments, and Alaska Natives' cultural traditions and access to subsistence resources.

DATES: This rule becomes effective on September 13, 2016.

The incorporation by reference of certain publications listed in the rule is approved by the Director of the Federal Register as of September 13, 2016.

ADDRESSES: Comments and material received from the public, as well as documents mentioned in this preamble as being available in the docket, are part of docket BSEE–2013–0011 and are available for inspection or copying at the Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. You may also find this docket on the Internet by going to *http://www.regulations.gov,* and searching for BSEE–2013–0011.

Materials incorporated by reference in this final rule may be inspected by appointment at BOEM and BSEE Headquarters, 45600 Woodland Road, Sterling, Virginia 20166, or at the BOEM and BSEE Alaska Regional Offices, 3801 Centerpoint Drive, Suite 400 or Suite 500, Anchorage, Alaska 99503, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. To make an appointment, call (202) 258–1518.

FOR FURTHER INFORMATION CONTACT: Mark E. Fesmire, BSEE, Alaska Regional Office, *mark.fesmire@bsee.gov,* (907) 334–5300; John Caplis, BSEE, Oil Spill Preparedness Division, *john.caplis@bsee.gov,* (703) 787–1364; or David Johnston, BOEM, Alaska Regional Office, *david.johnston@boem.gov,* (907) 334–5200. To see a copy of any relevant information collection request submitted to Office of Management and Budget (OMB), go to *http://www.reginfo.gov* (select Information Collection Review).

SUPPLEMENTARY INFORMATION:

Executive Summary

Although there is currently a comprehensive OCS oil and gas regulatory program, there is a need for new and revised Arctic-specific regulatory measures for exploratory drilling conducted by floating drilling vessels and "jack-up rigs" (collectively known as mobile offshore drilling units or (MODU)) in the Beaufort Sea and Chukchi Sea Planning Areas (defined in this final rule as the Arctic OCS). The United States (U.S.) Arctic region, as recognized and defined in the U.S. Arctic Research and Policy Act of 1984, as amended, encompasses an extensive marine and terrestrial area; however, this final rule focuses solely on the OCS within the Beaufort Sea and Chukchi Sea Planning Areas.

On February 24, 2015, BOEM and BSEE published a Notice of Proposed Rulemaking (NPRM) in the **Federal Register** entitled, "Oil and Gas and Sulfur Operations in the Outer Continental Shelf—Requirements for Exploratory Drilling on the Arctic Outer Continental Shelf" (80 FR 9916). We received 1,311 letters to the docket, from over 100,000 individual commenters on the NPRM. Additionally, BOEM and BSEE engaged in Government-to-Government Tribal consultations and Government-to-Alaska Native Claims Settlement Act (ANCSA) Corporations consultations prior to and after publication of the NPRM, to discuss the subject matter of the proposed rule and to solicit input on the development of the final rule. In the development of the NPRM and this final rule, BOEM and BSEE undertook extensive environmental and safety reviews of potential oil and gas operations on the Arctic OCS. After considering comments on the NPRM, Tribal and other consultations, the environmental analysis, and DOI's direct experience from Shell's 2012 and 2015 Arctic operations, BOEM and BSEE concluded that finalizing additional exploratory drilling regulations will enhance existing regulations and is appropriate for establishing a more holistic Arctic OCS oil and gas regulatory framework.

The U.S Arctic region is known for its oil and gas resource potential, its vibrant ecosystems, and the Alaska Native communities, which rely on the Arctic's resources for subsistence use and cultural traditions. The region is characterized by extreme environmental conditions, geographic remoteness, and a relative lack of fixed infrastructure and existing operations. These are key factors in considering the feasibility, practicality, and safety of conducting offshore oil and gas activities on the Arctic OCS. This final rule will help to ensure that Arctic OCS exploratory drilling operations are conducted in a safe and responsible manner while taking into account the unique conditions of Arctic OCS drilling activities and Alaska Natives' cultural traditions and access to subsistence resources.

This final rule adds to and revises existing regulations in 30 CFR parts 250, 254, and 550 for Arctic OCS oil and gas activities and focuses on exploratory drilling activities that use MODUs and related operations during the Arctic OCS open-water drilling season. The final rule does not preclude exploratory drilling on the Arctic OCS conducted in the future using other drilling technologies (*e.g.,* use of a land rig on grounded or land-fast ice). Exploratory drilling operations using technologies other than MODUs are outside the scope of the final rule and would be evaluated under the existing OCS oil and gas regulatory program, as may be amended. The final regulations address a number of important issues and objectives, including ensuring that each operator:

1. Designs and conducts exploration programs in a manner that accounts for Arctic OCS conditions;
2. Develops an integrated operations plan (IOP) that addresses all phases of its proposed Arctic OCS exploration program, and submits the IOP to BOEM at least 90 days in advance of filing its Exploration Plan (EP);

3. Has access to, and the ability to promptly deploy, Source Control and Containment Equipment (SCCE) while drilling below, or working below, the surface casing;

4. Has access to a separate relief rig located in a geographic position to be able to timely drill a relief well under the conditions expected at the site in the event of a loss of well control;

5. Has the capability to predict, track, report, and respond to ice conditions and adverse weather events;

6. Effectively manages and oversees contractors; and,

7. Develops and implements an Oil Spill Response Plan (OSRP) that is designed and executed in a manner that accounts for the unique Arctic OCS operating environment, and has the necessary equipment, training, and personnel for oil spill response on the Arctic OCS.

The final rule furthers the Nation's stewardship of the Arctic's environment and resources, and establishes specific operating models and requirements for the extreme, changing conditions that exist on the Arctic OCS. The regulations will require comprehensive planning of operations, especially for emergency response and safety systems. A goal of the final rule is to encourage the identification of operational risks early in the planning process and to encourage operators to plan for how to avoid and/or mitigate those risks. The requirements in the final rule also aim to ensure that plans meet the challenges presented by Arctic conditions and are executed in a safe and environmentally protective manner.

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  K. Paperwork Reduction Act (PRA)
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  M. Data Quality Act
  N. Effects on the Nation's Energy Supply (E.O. 13211)
  O. Clarity of This Regulation

List of Acronyms and References

LIST OF ACRONYMS AND REFERENCES

60-Day Report	Report to the Secretary of the Interior, Review of Shell's 2012 Alaska Offshore Oil and Gas Exploration Program.
ACPs	Area Contingency Plans.
AEWC	Alaska Eskimo Whaling Commission.
ANCSA	Alaska Native Claims Settlement Act.
APD	Application for Permit to Drill.
API	American Petroleum Institute.
APM	Application for Permit to Modify.
Arctic OCS	OCS within the Beaufort Sea and Chukchi Sea Planning Areas.
BAST	Best Available and Safest Technology.
BOEM	Bureau of.
BOP	Blowout Preventer.
BSEE	Bureau of Safety and Environmental Enforcement.
CAA	Conflict Avoidance Agreement.
CAP	Corrective Action Plan.
CFR	Code of Federal Regulations.
COCP	Critical Operations and Curtailment Plan.
CWA	Clean Water Act.
Department	Department of the Interior.
DOCD	Development Operations Coordination Document.
DOI	Department of the Interior.
DPP	Development and Production Plan.
EA	Environmental Assessment.
E.O.	Executive Order.
E.O. 13580 Alaska Energy Permitting IWG.	Interagency Working Group on Coordination of Domestic Energy Development and Permitting in Alaska.
EP	Exploration Plan.
EPA	Environmental Protection Agency.
ESA	Endangered Species Act.
FOSC	Federal On Scene Coordinator.
HPHT	High Pressure High Temperature.
IACS	International Association of Classification Societies.
IBR	Incorporation by Reference.
IC	Information Collection.

LIST OF ACRONYMS AND REFERENCES—Continued

ICAS	Inupiat Community of the Arctic Slope.
ICS	Incident Command System.
IEC	International Electrotechnical Commission.
IMH	Incident Management Handbook.
IMO	International Maritime Organization.
IMP	Ice Management Plan.
INC	Incident of Noncompliance.
IOGP	International Association of Oil and Gas Producers.
IOP	Integrated Operations Plan.
IPD	Interim Policy Document.
IPIECA	International Petroleum Industry Environmental Conservation Association.
IQA	Information Quality Act.
IRFA	Initial Regulatory Flexibility Analysis.
ISO	International Organization of Standardization.
MMPA	Marine Mammal Protection Act.
MMS	Minerals Management Service.
MOA	Memorandum of Agreement.
MODU	Mobile Offshore Drilling Unit.
MPD	Managed Pressure Drilling.
MWD	Measurement while Drilling.
NAICS	North American Industry Classification System.
NARA	National Archives and Records Administration.
NCP	National Oil and Hazardous Substances Pollution Contingency Plan.
NEPA	National Environmental Policy Act of 1969.
NMFS	National Marine Fisheries Service.
NOAA	National Oceanic and Atmospheric Administration.
NPC	National Petroleum Council.
NPDES	National Pollutant Discharge Elimination System.
NPRM	Notice of Proposed Rulemaking.
NSAR	President's National Strategy of the Arctic Region, issued May 2013.
NTL	Notice to Lessees and Operators.
NWS	National Weather Service.
OCS	Outer Continental Shelf.
OCSLA	Outer Continental Shelf Lands Act.
ODCE	Ocean Discharge Criteria Evaluations.
OEM	Original Equipment Manufacturer.
OIRA	Office of Information and Regulatory Affairs.
OMB	Office of Management and Budget.
OPA	Oil Pollution Act of 1990.
OSRO	Oil Spill Response Organization.
OSRP	Oil Spill Response Plan.
PHMSA	Pipeline and Hazardous Materials Safety Administration.
PRA	Paperwork Reduction Act.
PREP	Preparedness for Response Exercise Program.
RCPs	Regional Contingency Plans.
RFAI	Requests for Additional Information.
RIA	Regulatory Impact Analysis.
RMROL	Realistic Maximum Response Operating Limits.
RP	Recommended Practice.
RTM	Real-Time Monitoring.
SCCE	Source Control and Containment Equipment.
SCSC	Source Control Support Coordinator.
Secretary	Secretary of the Interior.
SEMS	Safety and Environmental Management Systems.
SID	Subsea Isolation Device.
SINTEF	Scientific and Industrial Research at the Norwegian Institute of Technology.
SOSC	State on Scene Coordinator.
TAP	Technical Assessment Program.
UMRA	Unfunded Mandates Reform Act of 1995.
U.S.	United States.
USCG	U.S. Coast Guard.
USFWS	U.S. Fish and Wildlife Service.
WCD	Worst Case Discharge.

I. Introduction

In May 2013, President Obama issued a document entitled, "National Strategy for the Arctic Region" (NSAR). The President affirmed that emerging economic opportunities exist in the region, but that ". . . we must exercise responsible stewardship, using an integrated management approach and making decisions based on the best available information, with the aim of promoting healthy, sustainable, and resilient ecosystems over the long term." The NSAR is intended, among other things, to "reduce our reliance on imported oil and strengthen our Nation's energy security" by working with stakeholders to enable "environmentally responsible production of oil and natural gas." To provide responsible stewardship of the

Arctic's environment and resources, the NSAR emphasizes the need for integrated and balanced management techniques.

Furthermore, the NSAR acknowledges the potential international implications of Arctic oil and gas activities for "other Arctic states and the international community as a whole." The U.S. has committed to do its part to "keep the Arctic region prosperous, environmentally sustainable, operationally safe, secure, and free of conflict[.]" One primary objective outlined in the implementation plan for the NSAR is to "reduce the risk of marine oil pollution while increasing global capabilities for preparedness and response to oil pollution incidents in the Arctic." (available at: *http://www.whitehouse.gov/sites/default/files/docs/implementation_plan_for_the_national_strategy_for_the_arctic_region_-_fi....pdf*). The NSAR is an example of the types of action the U.S. is taking to implement its obligations under international agreements, such as the Arctic Council's Agreement on Cooperation on Marine Oil Pollution Preparedness and Response in the Arctic (available at *http://arctic-council.org/eppr/agreement-on-cooperation-on-marine-oil-pollution-preparedness-and-response-in-the-arctic/*).

A. Resource Potential

The Arctic OCS region is estimated to contain a vast amount of undiscovered, technically recoverable oil and gas. Most of the Alaska OCS resource potential is located off the Arctic coast within the Chukchi Sea and Beaufort Sea Planning Areas. According to BOEM's 2016 Assessment of Undiscovered Technically Recoverable Oil and Gas Resources of the Nation's Outer Continental Shelf (mean estimates available at *http://www.boem.gov/National-Assessment-2016/*, there are approximately 23.6 billion barrels of technically recoverable oil and about 104.4 trillion cubic feet of technically recoverable natural gas in the combined Beaufort Sea and Chukchi Sea Planning Areas. This resource potential has intermittently received considerable attention from the oil and gas industry over several decades. The U.S. government has responded to this interest by holding lease sales offering millions of acres resulting in hundreds of leases, and the oil and gas industry has conducted Arctic exploration activities beginning in the 1970s.

B. Integrated Arctic Management

As ocean and seasonal conditions continue to change in the U.S. Arctic, both commercial and recreational activities will increase as more areas of water open up for longer periods of time due to the increased melting of sea ice. The decrease in summer sea ice raises legitimate concerns regarding changes to the environment and the Arctic resources that Alaska Natives depend on for survival and cultural traditions. Consistent with the Outer Continental Shelf Lands Act (OCSLA), BOEM and BSEE, the Bureaus responsible for managing oil and gas resources on the Arctic OCS, are finalizing these regulations that take into account the needs of the multiple users who have an interest in the future of the U.S. Arctic region (*see* 43 U.S.C. 1332(6)).

The U.S. has a longstanding interest in the orderly development of oil and gas resources on the Arctic OCS, while also seeking to ensure the protection of its environment and communities. The U.S. has proceeded with Arctic OCS oil and gas development to ensure that laws, regulations, and policies are created and implemented based on a thorough examination of the multiple factors at play in this unique environment. BOEM and BSEE have conducted extensive research on potential oil and gas activities on the OCS in anticipation of operations (*see, e.g., www.bsee.gov/Technology-and-Research/Technology-Assessment-Programs/Categories/Arctic-Research/*), and have also evaluated the potential environmental effects of such activities (*see, e.g., http://www.boem.gov/akstudies/*). These research projects, along with other initiatives, form the basis for the most recent National policies and directives regarding Alaska OCS oil and gas development, all of which have guided this final rule.

Coordinating the future uses of the U.S. Arctic region will require integrated action between and among Federal, State, municipal and tribal governmental entities. On July 12, 2011, President Obama signed Executive Order (E.O.) 13580, establishing an Interagency Working Group on Coordination of Domestic Energy Development and Permitting in Alaska (E.O. 13580 Alaska Energy Permitting IWG), chaired by the Deputy Secretary of the Interior. The E.O. 13580 Alaska Energy Permitting IWG is composed of representatives from the DOI, Department of Defense, Department of Commerce, Department of Agriculture, Department of Energy, Department of Homeland Security, and the Environmental Protection Agency (EPA).[1] It is charged with facilitating "coordinated and efficient domestic energy development and permitting in Alaska while ensuring that all applicable [health, safety, and environmental protection] standards are fully met" (E.O. 13580, sec. 1).

The E.O. 13580 Alaska Energy Permitting IWG's report entitled, "Managing for the Future in a Rapidly Changing Arctic, A Report to the President" (March 2013) (*see http://www.afsc.noaa.gov/publications/misc_pdf/iamreport.pdf*), was the result of substantial collaboration and also plays a significant role in shaping U.S. Arctic policies. Further, the President signed E.O. 13689, *Enhancing Coordination of National Efforts in the Arctic* on January 21, 2015. This E.O. states the policy: "The Arctic has critical long-term strategic, ecological, cultural, and economic value, and it is imperative that we continue to protect our national interests in the region, which include: national defense; sovereign rights and responsibilities; maritime safety; energy and economic benefits; environmental stewardship; promotion of science and research; and preservation of the rights, freedoms, and uses of the sea as reflected in international law." An Arctic Executive Steering Committee was established to provide guidance to Federal departments and agencies and to enhance coordination of Federal Arctic policies.

C. Overview of Regulations

Although there is currently a comprehensive OCS oil and gas regulatory program, DOI engagement with partners and stakeholders[2] and comments on the NPRM underscore the need for new and enhanced regulatory measures for Arctic OCS exploratory drilling by MODUs. For purposes of this rulemaking, exploratory drilling is defined as "[a]ny drilling conducted for the purpose of searching for commercial quantities of oil, gas, and sulfur, including the drilling of any additional well needed to delineate any reservoir to enable the lessee to decide whether to proceed with development and production."

This final rule defines the "Arctic OCS" as the Beaufort Sea and Chukchi Sea Planning Areas, as described in the

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[1] The Office of the Federal Coordinator for Alaska Natural Gas Transportation Projects was represented on the E.O. 13580 Alaska Energy Permitting IWG, but closed on March 7, 2015, due to lack of funding. Its Web site, *Arcticgas.gov*, is being maintained, but not updated, by the U.S. Arctic Research Commission, with assistance from Alaska Resources Library & Information Services (ARLIS) at the University of Alaska Anchorage. *See http://www.arcticgas.gov/*.

[2] Tribes, State and local governments, and Federal agencies are "partners." "Stakeholders" are non-governmental organizations, industry, and other entities with an interest in this rulemaking.

Proposed Final OCS Oil and Gas Leasing Program for 2012—(June 2012) (available at: *www.boem.gov/uploadedFiles/BOEM/Oil_and_Gas_Energy_Program/Leasing/Five_Year_Program/2012-2017_Five_Year_Program/PFP%2012-17.pdf* (see pp.21–24)).[3] This definition is added to §§ 250.105, 254.6, and 550.105. As described below, BOEM and BSEE determined that these areas are both the subject of exploration and development interest and subject to conditions that present significant challenges to such operations.

This final rule applies to Arctic OCS exploratory drilling activities that use MODUs (*e.g.*, jack-ups and drillships) and related operations during the Arctic open-water drilling season (generally late June to early November). We note that, because this rulemaking is applicable only to MODUs conducting exploration drilling, the provisions finalized here do not apply to shallow water drilling from gravel islands or the use of a land rig on grounded or land-fast ice and do not prohibit these or other methods of exploratory drilling operations on the Arctic OCS.

This final rule builds on and codifies input received from partners and stakeholders, comments to the proposed rule, as well as key components of the 2012 and 2015 Arctic exploratory drilling programs. DOI released in 2013 a "Report to the Secretary of the Interior, Review of Shell's 2012 Alaska Offshore Oil and Gas Exploration Program" (60-Day Report) (available at *http://www.doi.gov/news/pressreleases/upload/Shell-report-3-8-13-Final.pdf*). The 60-Day Report identified a number of lessons learned and recommended practices to ensure future Arctic oil and gas exploration activities would be carried out in a safe and responsible manner.

Shell's exploratory operations proceeded in 2015 without any unexpected drilling-related problems, and it safely drilled its well to a total depth of 6800 feet. On September 28, 2015, Shell announced that it had found indications of oil and gas in the well, but stated that the results were not sufficient to warrant further exploration of the prospect, and the well was to be plugged and abandoned in accordance with BSEE regulations. Shell subsequently announced it was ceasing further exploration activity in offshore Alaska for the foreseeable future.[4]

BOEM and BSEE have undertaken extensive environmental and safety reviews of potential oil and gas operations on the Arctic OCS. These reviews, along with concerns expressed by environmental organizations and Alaska Natives, as well as other stakeholders, highlight the need to develop additional measures specifically tailored to the operational and environmental conditions of the Arctic OCS. Arctic OCS operations can be complex, and there are challenges and operational risks throughout every phase of an exploratory drilling program.

This final rule is a combination of prescriptive and performance-based requirements that address a number of important issues and objectives, including, but not limited to, ensuring that operators:

1. Design and conduct exploration programs in a manner that accounts for Arctic OCS conditions (*e.g.*, using equipment and processes that are capable of performing effectively and safely under extreme weather and sea conditions and in remote locations with relatively limited infrastructure);
2. Develop an IOP that addresses all phases of an Arctic OCS exploration program and submit the IOP to BOEM at least 90 days in advance of filing an EP;
3. Have access to, and the ability to promptly deploy, SCCE while drilling below, or working below, the surface casing;
4. Have access to a separate relief rig located in a geographic position to be able to timely drill a relief well under the conditions expected at the site;
5. Have the capability to predict, track, report, and respond to ice conditions and adverse weather events;
6. Effectively manage and oversee contractors; and
7. Develop and implement OSRPs that are designed in a manner that accounts for the unique Arctic OCS operating environment and that describe the availability of the necessary equipment, training, and personnel for oil spill response on the Arctic OCS.

D. Costs and Benefits of Final Rule

The Final Regulatory Impact Analysis (RIA) for this final rule estimates that the new requirements could result in compliance costs for the industry of $2.05 billion under 3-percent discounting and $1.74 billion under 7-percent discounting over 10 years. The provisions of the rule subsumed within the regulatory baseline are estimated to cost $1.83 billion under 3-percent discounting and $1.51 billion under 7-percent discounting over the 10-year analysis period. As discussed in Section V.B of the preamble, the baseline includes the estimated costs associated with current regulatory requirements and industry standards. While the economic and other benefits of the final rule—based primarily on preventing or reducing the severity or duration of catastrophic oil spills—are difficult to quantify, BOEM and BSEE have determined that it is appropriate to proceed with this final rule. Although the probability of a catastrophic oil spill is low, the *Deepwater Horizon* oil spill demonstrated that even such low probability events can have devastating human, economic and environmental results if they occur.

Reducing the risks of Arctic OCS operations is particularly important because of the unique significance to Alaska Natives of the marine mammals, fish, and migratory birds, in the lands and waters around the Arctic OCS. Ensuring a continuing opportunity to harvest these subsistence resources is critical for protecting Alaska Natives' health, livelihood, and culture. Additionally, adequately protecting the health of the Arctic ecosystem, including the sensitive environment and wildlife, is particularly important and highly valued. Thus, the impact of a catastrophic oil spill, while a remote possibility, would have extremely high cultural and societal costs, and prevention of such a catastrophe would have correspondingly high cultural and societal benefits.

The requirements of the rule—specifically tailored to the Arctic OCS—provide additional specificity regarding BOEM's and BSEE's expectations for safe and responsible development of U.S. Arctic resources and outline the particular actions that lessees, owners, and operators must take to meet those expectations. BOEM and BSEE do not anticipate that these requirements, or their associated costs, will prevent lessees and operators from conducting exploratory drilling on their leases. In pursuing such operations, Arctic OCS lessees and operators are well aware of the significant challenges presented by Arctic OCS conditions, and the final rule largely reflects clarification and codification of the Bureaus' expectations under existing regulations and industry standards for the relevant operations. In fact, the additional clarity and specificity provided by the final rule should assist the oil and gas industry to plan better and to more effectively conduct exploratory drilling on the Arctic OCS with lower risk. As discussed later in this final rule, the positive impact of such production on U.S. energy independence and energy security could be substantial if hydrocarbon resources can be extracted and marketed economically. Thus, this final rule would help achieve the NSAR goals of protecting the unique and sensitive Arctic ecosystems, as well as the subsistence-based health and culture of nearby Alaska Native communities, while reducing reliance on imported oil and strengthening National energy security.

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[3] This final rule uses and defines terms that may be similar to terms used in other programs by other Federal agencies; however, the terms and definitions used in this final rule are intended to apply only to the BSEE and BOEM regulatory programs covered by this final rule, unless otherwise noted.

[4] Shell update of Alaska exploration, Press release (September 28, 2015) (available at *http://www.shell.com/global/aboutshell/media/news-and-media-releases/2015/shell-updates-on-alaska-exploration.html*).

E. Availability of Incorporated Documents for Public Viewing

BSEE frequently uses standards (*e.g.,* codes, specifications, Recommended Practices (RP)) developed through a consensus process, facilitated by standards development organizations and with input from the oil and gas industry, as a means of establishing requirements for activities on the OCS. BSEE may incorporate these standards into its regulations without republishing the standards in their entirety in the Code of Federal Regulations (CFR), a practice known as incorporation by reference. The legal effect of incorporation by reference is that the incorporated standards become regulatory requirements. This incorporated material, like any other properly issued regulation, has the force and effect of law, and BSEE holds operators, lessees and other regulated parties accountable for complying with the documents incorporated by reference in our regulations. We currently incorporate by reference over 100 consensus standards in BSEE's regulations governing offshore oil and gas operations (*see* 30 CFR 250.198).

Federal regulations, at 1 CFR part 51, govern how BSEE and other Federal agencies incorporate various documents by reference. Agencies may only incorporate a document by reference by publishing in the **Federal Register** the document title, edition, date, author, publisher, identification number, and other specified information. The Director of the **Federal Register** must approve each publication incorporated by reference in a final rule. Incorporation by reference of a document or publication is limited to the specific edition cited by the agency in the final rule and approved by the Director of the Federal Register.

BSEE incorporates by reference in its regulations many oil and gas industry standards in order to require compliance with those standards in offshore operations. When a copyrighted publication is incorporated by reference into BSEE regulations, BSEE is obligated to observe and protect that copyright. BSEE provides members of the public with Web site addresses where these standards may be accessed for viewing—sometimes for free and sometimes for a fee. Standards development organizations decide whether to charge a fee. One such organization, the American Petroleum Institute (API), provides free online public access to review its key industry standards, including a broad range of technical standards. These standards represent almost one-third of all API standards and include all that are safety-related or are incorporated into Federal regulations. One of those standards is incorporated by reference in this final rule. In addition to the free online availability of the standard for viewing on API's Web site, hardcopies and printable versions are available for purchase from API. The API Web site address is: *http://www.api.org/publications-standards-and-statistics/publications/government-cited-safety-documents.*[5]

For the convenience of members of the viewing public who may not wish to purchase or view these incorporated documents online, they may be inspected at BSEE's office, 45600 Woodland Road, Sterling, Virginia 20166; phone: 703–787–1665.

F. Summary of Documents Incorporated by Reference

This rulemaking is substantive in terms of the content that is explicitly stated in the rule text itself, and it also incorporates by reference a technical standard concerning structures and pipelines for offshore Arctic conditions. A brief summary of the standard follows.

ANSI/API Recommended Practice 2N, Recommended Practice for Planning, Designing, and Constructing Structures and Pipelines for Arctic Conditions

This standard was developed in response to the offshore industry's demand for a coherent and consistent definition of methodologies to design, analyze, and assess arctic and cold region offshore structures. This standard also addresses issues such as topsides, winterization, and escape, evacuation, and rescue that go beyond what is strictly necessary for the design, construction, transportation, installation, and decommissioning of the structure. These issues are essential for offshore operations in arctic and cold region conditions and they are not covered in other standards. When future editions of this and other standards are prepared, effort will be made to avoid duplication of scope.

II. Background

A. Statutory and Regulatory Overview

1. Procedural History

On February 24, 2015, BOEM and BSEE published an NPRM in the **Federal Register** entitled, "Oil and Gas Operations in the Outer Continental Shelf—Requirements for Exploratory Drilling on the Arctic Outer Continental Shelf" (80 FR 9916). In response to several commenters' requests, we published a 30-day extension of the comment period for the NPRM on April 20, 2015 (80 FR 21670). We received 1,311 letters to the docket for the rulemaking, from over 100,000 individual commenters on the NPRM. We summarize these comments in the preamble of this final rule in Section IV.B *Discussion of and Responses to Comments.* Between June 6, 2013 and July 15, 2016, BOEM and BSEE held several meetings as part of tribal consultations on this rulemaking in the following Alaskan locations: Kotzebue, Point Hope, Point Lay, Barrow, Wainwright, and via teleconference with Nuiqsut. Comments received from Alaska Native Tribes and ANCSA Corporations, both written and oral, are summarized in Section IV.B. Discussion of these consultations with Alaska Native Tribes and Corporations appears in the preamble at Section V.I *Consultation with Indian Tribes (E.O 13175).*

2. OCSLA

The OCSLA, 43 U.S.C. 1331 *et seq.,* was first enacted in 1953, and substantially amended in 1978, when Congress established a national policy of making the OCS "available for expeditious and orderly development, subject to environmental safeguards, in a manner which is consistent with the maintenance of competition and other national needs" (43 U.S.C. 1332(3)). In addition, Congress emphasized the need to develop OCS mineral resources in a safe manner "by well-trained personnel using technology, precautions, and techniques sufficient to prevent or minimize the likelihood of blowouts, loss of well control, fires, spillages, physical obstruction to other users of the waters or subsoil and seabed, or other occurrences which may cause damage to the environment or to property, or endanger life or health" (43 U.S.C. 1332(6)). The Secretary of the Interior (Secretary) administers the OCSLA's provisions relating to the leasing of the OCS and regulation of mineral exploration and development operations on those leases. The Secretary is authorized to prescribe "such rules and regulations as may be necessary to carry out [OCSLA's] provisions" and "may at any time prescribe and amend such rules and regulations as [s]he determines to be necessary and proper in order to provide for the prevention of waste and conservation of the natural resources of the [OCS] . . ." which "shall, as of their effective date, apply to all operations conducted under a lease issued or maintained under the provisions of [OCSLA]" (43 U.S.C. 1334(a)).

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[5] To review these standards online, go to the API publications Web site at: *http://publications.api.org.* You must then log-in or create a new account, accept API's "Terms and Conditions," click on the "Browse Documents" button, and then select the applicable category (*e.g.,* "Exploration and Production") for the standard(s) you wish to review.

The Secretary delegated most of the responsibilities under the OCSLA to BOEM and BSEE, both of which are charged with administering and regulating aspects of the Nation's OCS oil and gas program (see § 250.101 and § 550.101). BOEM and BSEE work to promote safety, protect the environment, and conserve offshore resources through vigorous regulatory oversight.

BOEM manages the development of the Nation's offshore energy resources in an environmentally and economically responsible way. BOEM's functions include leasing; exploration, development and production plan administration and review; environmental analyses to ensure compliance with the National Environmental Policy Act of 1969 (NEPA); environmental studies; resource evaluation; economic analysis; complying with other Federal laws (*e.g.*, the Endangered Species Act (ESA)); and management of the OCS renewable energy program.

BSEE performs offshore regulatory oversight and enforcement to ensure safety and environmentally sound performance during operations, and the conservation of OCS resources, by, among other things, evaluating drilling permits, and conducting inspections to ensure compliance with laws, regulations, lease terms, and approved plans and permits.

Prior to commencing exploration for oil and gas on the OCS, OCSLA and its implementing regulations (43 U.S.C. 1340(c)(1); § 550.201(a)) require lessees to submit an EP to BOEM for approval. An EP must include information such as a schedule of anticipated exploration activities, equipment to be used, the general location of each well to be drilled, and any other information deemed pertinent by BOEM (§§ 550.211 through 550.228).

However, approval of an EP does not by itself permit the lessee to proceed with exploratory drilling. After the EP is approved, the lessee must submit to BSEE an Application for Permit to Drill (APD), which BSEE must approve before a lessee may drill a well (43 U.S.C. 1340(d); § 250.410)). The APD must be consistent with the approved EP and include information on the well location, the drilling design and procedures, casing and cementing programs, the diverter and Blowout Preventer (BOP) systems, MODU (if one is used), and additional information requested by the District Manager.

BOEM evaluates EPs, and BSEE evaluates APDs, to determine whether the operator's proposed activities meet the OCSLA's standards and each Bureau's regulations governing OCS exploration. The regulatory requirements include, but are not limited to, ensuring that the proposed drilling operation:

i. Conforms to OCSLA, as amended, its applicable implementing regulations, lease provisions and stipulations, and other applicable laws;

ii. Is conducted in a safe manner;

iii. Conforms to sound conservation practices and protects the rights of the U.S. in the mineral resources of the OCS;

iv. Does not unreasonably interfere with other uses of the OCS; and

v. Does not cause undue or serious harm or damage to the human, marine, or coastal environments (§§ 250.101 and 250.106; 550.101 and 550.202).

Based on these evaluations, BOEM and BSEE will approve the lessee's (or operator's) EP and APD, require the lessee (or operator) to modify its submissions, or disapprove the EP or APD (§§ 250.410; 550.233).

3. The Oil Pollution Act of 1990 (OPA) and Clean Water Act (CWA)

Congress passed the OPA, 33 U.S.C. 2701 *et seq.*, following the *Exxon Valdez* oil spill. The OPA amended the CWA, 33 U.S.C. 1251 *et seq.*, by, among other things, adding OSRP requirements for offshore facilities. The OPA provides for prompt federally coordinated responses to offshore oil spills and for compensation of spill victims. It also calls for the issuance of regulations prohibiting owners and operators of offshore facilities from operating or handling, storing, or transporting oil until:

i. They have prepared and submitted "a plan for responding, to the maximum extent practicable, to a worst case discharge (WCD), and to a substantial threat of such a discharge, of oil . . .;"

ii. The plan "has been approved by the President;" and

iii. The "facility is operating in compliance with the plan" (OPA section 4202(a), codified at 33 U.S.C. 1321(j)(5)(A)(i) and (F)(i)–(ii)).

E.O. 12777 (October 18, 1991) delegated to the Secretary the functions of 33 U.S.C. 1321(j)(5) and (j)(6)(A) related to offshore facilities (other than deep water ports). This includes the promulgation of regulations governing the obligation to prepare and submit OSRPs, the review and approval of OSRPs, and the periodic verification of spill response capabilities related to these plans. Those applicable regulations are administered by BSEE and are at parts 250 and 254. E.O. 12777 also delegated to the Secretary the authority to implement, for offshore facilities, 33 U.S.C. 1321(j)(1)(C), which provides for the issuance of regulations "establishing procedures, methods, and equipment and other requirements for equipment to prevent discharges of oil and hazardous substances from . . . offshore facilities, and to contain such discharges."

B. Factual Overview of the Arctic OCS Region

1. Arctic OCS Oil and Gas Activity

There has been a renewed interest in the oil and gas potential of the Alaska OCS since the first exploratory wells were drilled in the late 1970s. The majority of exploratory drilling north of the Arctic Circle has occurred where the greatest oil and gas resource potential exists, namely the Beaufort Sea and Chukchi Sea Planning Areas (*see* Figure 1). A total of 30 exploratory wells have been drilled on the Beaufort OCS since the first Federal OCS leases were offered, and more wells have been drilled beneath the near-shore Beaufort Sea under the jurisdiction of the State of Alaska. The Chukchi Sea Planning Area has a more limited history of leasing and exploration. Before 2012, only a total of five exploratory wells had been drilled there (between 1989 and 1991[6]), and no explored prospect was considered economically viable for development.

Until Shell's 2012 and 2015 exploratory operations, there had been only one exploratory well drilled on the Arctic OCS since 1994—the 2003 exploratory well near Prudhoe Bay in the Beaufort Sea (*see* BOEM Assessment of Undiscovered Technically Recoverable Oil and Gas Resources of the Nation's Outer Continental Shelf (2016). In 2012, Shell drilled two "top hole" wells (*i.e.*, a partial well not intended to enter hydrocarbon zones), one in the Chukchi Sea (Burger Prospect) and the other in the Beaufort Sea (Sivulliq). In 2015, Shell completed an exploratory well in the Burger prospect of the Chukchi Sea; however, according to Shell, indications of oil and gas were "not sufficient to warrant further exploration in the Burger prospect."[7]

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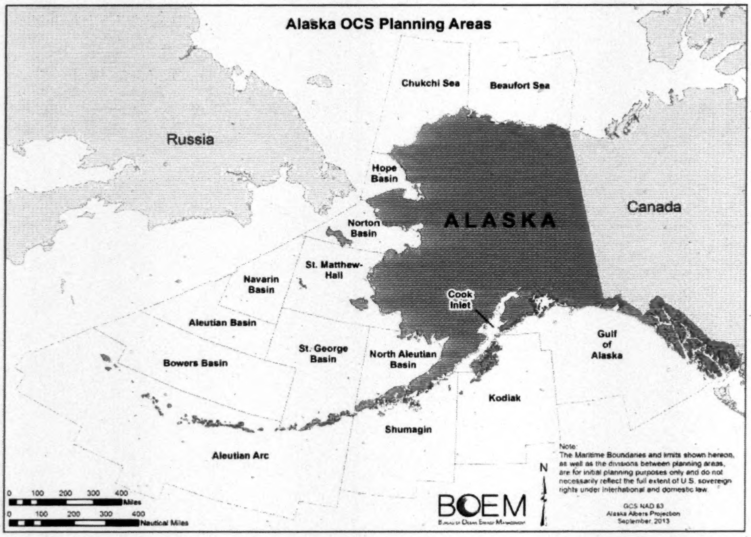
[6] *See* BOEM Alaska Region Web site available at *www.boem.gov/About-BOEM/BOEM-Regions/Alaska-Region/Historical-Data/Index.aspx.*


Alaska OCS Planning Areas
Chukchi Sea
Beaufort Sea
Russia
Hope Basin
ALASKA
Canada
Norton Basin
St. Matthew-Hall
Navarin Basin
Cook Inlet
Aleutian Basin
St. George Basin
North Aleutian Basin
Gulf of Alaska
Bowers Basin
Kodiak
Shumagin
Aleutian Arc
0 100 200 300 400 Miles
0 100 200 300 400 Nautical Miles
BOEM
N
Note:
The Maritime Boundaries and limits shown hereon, as well as the divisions between planning areas, are for initial planning purposes only and do not necessarily reflect the full extent of U.S. sovereign rights under international and domestic law.
GCS NAD 83
Alaska Albers Projection
September, 2013

[Figure 1]

With the exception of three OCS leases making up a portion of the Northstar oil field, currently operated by Hilcorp Alaska, LLC, from State submerged lands in the Beaufort Sea, no production has yet resulted from Alaska OCS leases.

2. Challenges to U.S. Arctic Oil and Gas Operations

The challenges to conducting operations and responding to emergencies in the extreme and variable environmental and weather conditions in the Arctic are demanding. Both the Beaufort Sea and Chukchi Sea Planning Areas experience sub-freezing temperatures during most of the year, extended periods of low-light visibility, significant fog cover in the summer, strong winds and currents, storms that produce freezing spray and dangerous sea states, snow, and significant ice cover. During the fall (September–November), conditions become increasingly inhospitable as air temperatures decrease, wind speeds increase, storms become more frequent, and sea ice begins to form, all of which make Arctic OCS exploratory drilling operations more challenging.[8] Other challenges to conducting operations and responding to emergencies on the Arctic OCS include the geographical remoteness and relative lack of established infrastructure to support oil and gas operations, as well as the presence of protected marine mammals and Alaska Native subsistence activities.

III. Regulations for Arctic OCS Exploratory Drilling

The existing OCS oil and gas regulatory regime is extensive and covers all offshore facilities or operations in any OCS region, as appropriate and applicable, including the Arctic OCS. BOEM and BSEE apply these regulations while overseeing OCS leasing, exploration, development, production, and decommissioning. Operators are subject to the same regulatory requirements, such as: Application procedures and information requirements for exploration, development, and production activities; pollution prevention and control; safety requirements for casing and cementing and the use of a BOP and diverter systems; design, installation, use and maintenance of OCS platforms to ensure structural integrity and safe and environmentally protective operations; decommissioning; development and implementation of Safety and Environmental Management Systems (SEMS); and preparation and submission of OSRPs (*see generally* 30 CFR parts 250, 254, and 550).

The existing regulations also contain provisions that apply to specific regions or atypical activities or operating conditions, especially, for example, where drilling occurs in deep water or in a "frontier" area (typically characterized by its remote location and limited infrastructure and operational history, such as the Arctic OCS region).

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[7] *http://www.shell.com/global/aboutshell/media/news-and-media-releases/2015/shell-updates-on-alaska-exploration.html.*

[8] *See* Environmental Assessments for Shell Offshore, Inc.'s Revised Outer Continental Shelf Lease Exploration Plan, Camden Bay, Beaufort Sea, Alaska (2011), Revised Outer Continental Shelf Lease Exploration Plan, Chukchi Sea, Alaska, Burger Prospect (2015), and Shell Gulf of Mexico, Inc.'s Revised Chukchi Sea Exploration Plan Burger Prospect (2011); BOEM Alaska Region Web site available at *http://www.boem.gov/About-BOEM/BOEM-Regions/Alaska-Region/Environment/Environmental-Analysis/Environmental-Impact-Statements-and-Major-Environmental-Assessments.aspx.*

In these situations, BOEM and BSEE have special requirements, such as information and design requirements for deep-water development projects (§§ 250.286 through 250.295); use of appropriate equipment, third-party audits, and contingency plans in frontier areas or other areas subject to subfreezing conditions (§§ 250.713(c) and 250.418(f)); the placement of subsea BOP systems in mudline cellars when drilling occurs in areas subject to ice-scouring (§ 250.738); and emergency plans and critical operations and curtailment procedures information in the Arctic OCS Region (§§ 550.220 and 550.251).

Though there is currently a generally applicable OCS oil and gas regulatory program, there is a need for new and amended regulatory measures specifically for Arctic OCS exploratory drilling by MODUs. This final rule, in combination with the existing regulations (which continue to apply to Arctic OCS operations unless otherwise expressly stated) will ensure that exploratory drilling operations are well planned from the outset and conducted safely and responsibly in relation to the unique Arctic environment and the local communities that are closely connected to the region and its resources. The key elements of the final rule are as follows:

A. Measures That Address Recommendations

The final rule addresses recommendations contained in several recent reports on OCS oil and gas activities, including the Arctic Council, Arctic Offshore Oil and Gas Guidelines (2009); the National Commission on the BP *Deepwater Horizon* Oil Spill and Offshore Drilling (2011); Ocean Energy Safety Advisory Committee Recommendations (2013); DOI's 60-Day Report (2013); the E.O. 13580 Alaska Energy Permitting IWG's report entitled, "Managing for the Future in a Rapidly Changing Arctic, A Report to the President" (March 2013); the NSAR (May 2013); the Arctic Council, Arctic Offshore Oil and Gas Guidelines: Systems Safety Management and Safety Culture (March 2014); and the National Petroleum Council (NPC), Arctic Potential: Realizing the Promise of U.S. Arctic Oil and Gas Resources (2015).

B. Approval of Alternate Procedures or Equipment

Numerous comments were submitted on the NPRM requesting a more performance-based approach to regulating exploratory drilling operations on the Arctic OCS. As discussed in depth in Section IV. B, *Discussion of and Responses to Comments,* we are aware that methods for source control and containment, securing a well, or killing and permanently plugging an out-of-control well on the Arctic OCS may include available technology for which there are no recognized industry standards or best practices. Accordingly, several of the final regulations are intended to convey an overarching performance requirement. For example, the operator must have the means available to secure any uncontrolled flow of hydrocarbons and kill the out-of-control well prior to seasonal ice encroachment. The regulations also provide prescriptive elements establishing means to comply with that requirement using existing, proven technology. And finally, the regulations provide a clear pathway towards alternative compliance measures to account for future technological advances. To further clarify our intent, we are revising the proposed language of both § 250.471, *What are the requirements for Arctic OCS source control and containment?,* and § 250.472, *What are the relief rig requirements for the Arctic OCS?* Paragraph (a) of § 250.471 is revised and a new paragraph (i) in § 250.471 is added to clearly convey the performance standard an operator must be able to demonstrate when requesting approval for alternative procedures or equipment to the SCCE—*i.e.,* response capabilities able to stop or capture the flow of an out-of-control well. Similarly, we are also revising the provisions at paragraphs (a) and (c) of § 250.472 to clarify that alternative procedures or equipment to the relief rig requirements must be capable of killing and permanently plugging an out-of-control well in less than 45 days.

Furthermore, existing regulations will continue to allow operators to use new and emergent technology on the OCS in certain circumstances and upon demonstrating adequate safety and environmental protection. Under § 250.141, *May I ever use alternate procedures or equipment?,* the District Manager or Regional Supervisor may approve the use of alternate procedures or equipment provided the operator can show the technology will meet or exceed the level of safety and environmental protection required by the current regulations. This provision enables operators to request approval for innovative technological advancements that may provide additional flexibility, provided the operator clearly establishes that such technology will meet or exceed the level of protection provided by the regulatory requirements. The operator is responsible for providing sufficient data to BSEE to adequately demonstrate the safety of the technology or operations. To obtain approval under § 250.141, an operator should submit information regarding its proposed alternate technology, which could include:

1. Laboratory tests results, test protocols, test procedures, testing methodologies, Quality Assurance/Quality Control provisions, manufacturer testing, and/or qualification or accreditation procedures implemented by an independent third party relevant to the performance characteristics of such equipment when used in a real world environment;
2. Actual operational performance of such equipment if previously used or currently being used in other areas under similar conditions; and
3. Additional studies, evaluations, or risk and/or hazards analyses relevant to the equipment or procedures under consideration.

C. IOP Requirement

During exploratory drilling operations on the Arctic OCS, operators may face substantial environmental challenges and operational risks throughout every phase of the endeavor, including preparations, mobilization, in-theater drilling operations, emergency response and preparedness, and demobilization. Thorough advanced planning is critical to mitigating these challenges and risks. One of the key components of this final rule is a requirement that operators explain how their proposed Arctic OCS exploratory drilling operations are fully integrated from start to finish in a manner that accounts for Arctic OCS conditions and that they provide this information to DOI at an early stage of the planning process.

This final rule requires that operators develop and submit IOPs to BOEM at least 90 days in advance of filing their EPs. The purpose of the IOP is to describe, at a strategic or conceptual level, how exploratory drilling operations will be designed, executed, and managed as an integrated endeavor from start to finish. The IOP is intended to be a concept of operations that includes a description of pertinent aspects of an operator's proposed exploratory drilling activities and supporting operations and how the operator will design and conduct its program in a manner that accounts for the challenges presented by Arctic OCS conditions. The primary issues that operators must address in their IOPs include:

1. Vessel and equipment designs and configurations;
2. The overall schedule of operations, including contractor work on critical components;
3. Mobilization and demobilization operations and maintenance schedule(s);
4. In-theater drilling program objectives and timelines for each objective;
5. Weather and ice forecasting and management capabilities;
6. Contractor management and oversight;
7. Operational safety principles;
8. Preparation and staging of spill response assets;
9. Impact on local community infrastructure, including but not limited to housing, energy supplies and services; and
10. Extent the project will rely on local community workforce and spill clean-up response capacity.

DOI recognizes that other Federal agencies have primary oversight responsibility for some of the previously listed activities. Upon receipt of the IOP, DOI would engage with members of the E.O. 13580 Alaska Energy Permitting IWG and promptly distribute the IOP to the State of Alaska and Federal government agencies making up the Alaska Energy Permitting IWG and others that are involved in the review, approval, or oversight of various aspects of OCS operations.

However, the IOP process does not entail any mechanism through which agencies can or must approve the operator's proposed activities described in the IOP. The IOP is intended to be a conceptual, informational document designed to ensure that an operator has planned to address risks associated with the full suite of regulated activities, and to provide the relevant regulatory agencies a preview of an operator's approach to regulatory compliance and integrated planning. It is also anticipated that an operator would already develop much of this requested information as a part of its internal planning for potential activity. Thus, the IOP enables relevant agencies to familiarize themselves, early in the planning process, with the operator's overall proposed program from start to finish. This, in turn, allows DOI and those agencies to coordinate and provide early input to the operator regarding potential issues presented by the proposed activities with respect to any future EP reviews and permitting requirements, including aspects of the program that might require additional details or refinement. The IOP requirement—and the final rule in general—will not, however, interfere with or supplant operators' obligations to comply with all other applicable Federal agency requirements. Each agency that receives an IOP would continue to review the relevant details of an operator's planned activities for compliance with that agency's regulatory requirements in the appropriate manner and at the appropriate time under its own regulatory program.

D. SCCE and Relief Rig Capabilities

In Arctic OCS exploratory drilling, there is a need for operators to demonstrate that they have access to, and could promptly deploy, well control and containment resources that would be adequate to respond to a loss of well control. This equipment is readily available and accessible in the Gulf of Mexico due to the level of activity in that area, but is not similarly available in the Arctic as a matter of normal course. Ensuring that operators have redundant protective measures in place is critical, as there is no guarantee that a single measure could control or contain a WCD. Therefore, BSEE is requiring that operators who use a MODU for Arctic OCS exploratory drilling must be able to stop or capture the flow of an out-of-control well by having access to, and the ability to deploy, SCCE (*e.g.*, a capping stack, cap and flow system, and containment dome) within the timeframes discussed in this final rule and that the SCCE be capable of functioning in Arctic OCS conditions.

BSEE is also requiring operators to have access to a separate relief rig, staged at a location such that it could arrive on site, drill a relief well, kill and abandon the original well, and abandon the relief well prior to expected seasonal ice encroachment at the drill site and in no event later than 45 days after the loss of well control. This equipment is fundamental to safe and responsible operations on the Arctic OCS, where existing infrastructure is sparse, the geography and logistics make bringing equipment and resources into the region challenging, and the time available to mount response operations is limited by changing weather and ice conditions, particularly at the end of the drilling season.

The 45-day period is the maximum time allowed for conducting relief rig operations. However, it is a performance-based requirement and leaves the means of compliance up to the operator. The operator may seek to demonstrate its ability to complete relief well operations in less than 45 days, subject to review by BOEM in the EP process under § 550.22(c)(4) and BSEE's review during the APD process under § 250.470(c). The length of the "shoulder season", or the period of time operators may not drill or work below the surface casing, depends upon how long operations related to the use of a relief rig can be expected to take. An operator must demonstrate how long it will take for a relief rig to arrive on site, drill a relief well, kill and abandon the original well and abandon the relief well prior to expected seasonal ice encroachment at the drill site (or trigger date). In evaluating this demonstration, consideration may be given to a number of factors, including but not limited to: The distance of drilling operations to the shore; available infrastructure; and the capacity and location of oil spill response equipment. The trigger date, established by BOEM (in consultation with the National Weather Service (NWS) and the operator)), restricts when the operator can drill or work below the surface casing in order to address risks associated with late season drilling and ensure an opportunity for spill response and cleanup in favorable conditions. BSEE notes the operator's actual timeframe to drill a relief well would be based on consideration of the distance between anticipated exploratory drilling sites, the availability of adequate staging locations for relief rigs, the length and complexity of rig transit, and the time necessary to complete the requisite operations once on-site. The 45-day maximum timeframe is intended to ensure a timely response and prevent an extended uncontrolled flow of hydrocarbons in the event of a loss of well control early in the open water season.

As discussed previously in Section III.B, we have revised the proposed language for the SCCE provisions at paragraph (a) of § 250.471 and added a new paragraph (i) in § 250.471, and revised the relief rig provisions at paragraphs (a) and (c) of § 250.472, to clearly state the standards operators must meet to satisfy the requirements, while also alternatively providing that operators may request approval of an alternate technology under existing § 250.141, if the operator can show the alternate technology will meet or exceed the level of safety and environmental protection provided by the SCCE and relief rigs requirements. This provision enables operators to request approval for innovative technological advancements that may provide additional flexibility.

E. Planning for the Variability and Challenges of the Arctic OCS Conditions

Reliable weather and ice forecasting play a significant role in ensuring safe operations on the Arctic OCS. Advanced forecasting and tracking technology, information sharing among industry and government, and local knowledge of the operating environment are essential to managing the substantial challenges and risks that Arctic OCS conditions pose for all OCS operations. In light of the threats posed by ice and extreme weather events, BOEM and BSEE require that operators include in their IOPs, EPs, and APDs, at appropriate levels of specificity for each document, a description of their weather and ice monitoring and forecasting capabilities for all phases of their exploration program, as well as their alert procedures and thresholds for activating ice and weather management systems. Once operations commence, this rule requires operators to:

1. Notify BOEM and BSEE immediately of any sea ice movement or condition that has the potential to affect operations or trigger ice management activities; and
2. Notify BSEE of the start and termination of ice management activities and submit written reports after completing such activities.

F. Arctic OCS Oil Spill Response Preparedness

Operators need to be prepared for a quick and effective response in the event of an oil spill on the Arctic OCS and be ready to coordinate activities with the Federal government and other stakeholders. The OSRPs and related activities should be tailored to the unique Arctic OCS operating environment to ensure that operators have the necessary equipment, training, and personnel. Among other things, this final rule establishes specific planning requirements to maximize the application of oil spill response technology and ensure a coordinated response system designed to address the challenges inherent to the U.S. Arctic region.

G. Reducing Pollution From Arctic OCS Exploratory Drilling Operations

Partners, primarily Alaska Native Tribes, as well as other stakeholders expressed concern that mud and cuttings from exploratory drilling could adversely affect marine species (*e.g.,* whales and fish) and their habitat and compromise the effectiveness of subsistence hunting activities. Existing environmental analyses support these concerns regarding petroleum based mud and cuttings and also demonstrate that such discharges could affect water quality, benthic habitat, and marine organisms within the localized area (*see, e.g.,* Shell Revised Outer Continental Shelf Lease Exploration Plan, Chukchi Sea, Alaska, Burger Prospect (2015)).

BSEE is requiring the capture of all petroleum-based mud and associated cuttings from Arctic OCS exploratory drilling operations to prevent the discharge of such pollutants into the marine environment. The new provision also clarifies the Regional Supervisor's discretionary authority to require that operators capture all water-based mud and associated cuttings from Arctic OCS exploratory drilling operations (after completion of the hole for the conductor casing) to prevent their discharge into the marine environment. The Regional Supervisor would exercise this discretion based on various factors, such as the proximity of exploratory drilling operations to subsistence hunting and fishing locations or the extent to which such discharges might cause marine mammals and birds to alter their migratory patterns in a manner that interferes with subsistence activities or might adversely affect marine mammals, fish, birds, or their habitat(s).

H. Oversight, Management, and Accountability of Operations and Contractor Support

An effective risk management framework at the beginning of a project incorporates many components, including planning, vessel design, contractor selection, and an assessment of regulatory requirements for all facets of the project. DOI is requiring that operators provide an explanation, starting in the IOP, at a conceptual level, of how they would apply their oversight and risk management protocols to both their personnel and their contractors to support safe and responsible exploratory drilling. These new regulations, in conjunction with DOI's existing regulations, require varying levels of information about operator safety and oversight management at progressive stages of the planning and approval process. This would start with the most general information and increase the level of detail with successive regulatory submittals, as the project proceeds from planning to implementation (*e.g.,* IOP to EP to APD).

In addition, the final rule requires Arctic OCS operators to:

1. Report threatening sea ice conditions and ice management activities, and unexpected operational issues that could result in a loss of well control;
2. Conduct real-time monitoring of various aspects of well operations,
3. Increase their SEMS auditing frequency; and,
4. Enhance their oil spill preparedness and response capabilities for Arctic OCS operations.

A summary of the changes that this final rule makes to the provisions proposed by the NPRM follows:

IV. Section-By-Section Discussion of Changes and Comments

This section summarizes the requirements proposed in the NPRM and how they are addressed in this final rule. Some of these provisions received no comments during the public comment period, while other provisions were supported or criticized by certain commenters. Section IV.A discusses the changes from the proposed to the final rule. Section IV.B discusses the public comments received and our responses to the comments. Many of these provisions and concepts are described in more detail above in Section III.

A. Summary of Key Changes From the NPRM

This section includes a description of how the final rule differs from the provisions proposed by the NPRM (80 FR 9916 (February 24, 2015)) along with an explanation of why the changes in the final rule are necessary. For a full discussion of comments and BOEM and BSEE responses, see section IV.B *Discussion of and Responses to Comments.*

Definitions. (§ 250.105)

BSEE is revising the proposed definition of "capping stack" to clarify that the required capping stack may be pre-positioned. Although the proposed definition did not preclude the use of a pre-positioned capping stack, in response to comments we determined a clarification to the definition of capping stack is appropriate. Accordingly, the addition of the clarification that the capping stack may be pre-positioned to the definition does not create a new category of capping stack, but instead clarifies that the use of a capping stack is not limited to subsea wellheads when surface BOPs are used. The revised definition makes clear that pre-positioned capping stacks may be used below subsea BOPs. BSEE will evaluate the use of a pre-positioned capping stack as a part of an operator's proposal on a case-by-case basis and approve their use when deemed technically and operationally appropriate, such as when the operator proposes to use a jack-up rig with surface trees.

When and how must I secure a well? (formerly § 250.402)

BSEE is revising the language of proposed § 250.402(c)(2) to clarify the circumstances under which BSEE may approve an equivalent means to satisfy the requirement that, in areas of ice scour, an operator must use a mudline cellar. We note the former § 250.402 was removed and reserved and the contents were moved to § 250.720 in the Blowout Preventer Systems and Well Control Final Rule (Well Control Rule) (80 FR 25888) published April 29, 2016. Therefore, the revisions to proposed § 250.402(c)(2) discussed here have been finalized as § 250.720(c)(2) in this rulemaking. The proposed rule provided that the operator may use an equivalent means to minimize the risk of damage to the well head. In response to comments expressing concern for the operational risks presented by the mudline cellar when using a jack-up rig, BSEE has clarified what an operator should show when requesting to utilize an equivalent alternative that minimizes risk to both the well head and the wellbore. Having a mudline cellar in place to protect the well head and wellbore provides an additional protection against a loss of well control and possible release of hydrocarbons to the environment. Accordingly, we have revised the language to clarify that an operator seeking approval of an equivalent means must show that a mudline cellar would create operational risks, as finalized at § 250.720(c) as set out in the regulatory text at the end of this document.

When must I pressure test the BOP system? (§ 250.447)

The proposed amendments to § 250.447(b) are not being included in the final rule. BSEE has decided to maintain the same 14-day BOP pressure test cycle on the Arctic OCS as is required elsewhere on the OCS. The existing regulation in paragraph (a)(4) of § 250.737 provides that the District Manager or Regional Supervisor may require more frequent testing if conditions or BOP performance warrant.

As discussed in Section IV.B, *Discussion of and Response to Comments,* many commenters to the proposed 7-day BOP testing requirement were concerned that increasing the number of pressure tests may reduce the reliability of the equipment by degrading the sealing capability of the elements within the BOP stack and would not necessarily demonstrate the future performance of the equipment. Commenters also asserted that the requirement for operators to stop drilling operations to perform a pressure test could ultimately increase the likelihood of an incident occurring. The BOP is a critical line of defense against loss of well control. Ensuring the proper functioning of the BOP is essential to all OCS drilling operations BSEE considered whether the integrity of BOPs could be compromised by Arctic OCS conditions; in particular, BSEE considered the possible effects of extreme weather conditions on BOPs maintained on surface vessels or facilities (such as jack-up rigs). At this time, pressure tests and functional tests are the primary methods for ensuring the performance of BOPs. BSEE considered these and other issues raised via public comments and has determined not to require increased testing frequency on the Arctic OCS.

BSEE recognizes the importance of ensuring the proper functioning of the BOP. Shell proposed a 7-day BOP testing cycle in 2012, and BSEE ultimately approved that approach for Shell. We proposed in the NPRM to require a similar testing frequency for all Arctic OCS exploratory drilling operations, due to the possibility that the integrity of BOPs could be compromised by Arctic conditions. BSEE specifically requested comments on the appropriateness of the proposed 7-day testing frequency to demonstrate the reliability of the equipment under Arctic conditions; any additional safety issues that might arise from this increased testing or that would be unique to Arctic operations; and all potential drilling impacts related to the proposed 7-day testing frequency.

Comments on BOP testing frequency fell largely into two groups: Supporters of the 14-day (or longer) test cycle and supporters of the 7-day test cycle. BSEE considered all of the comments, the information and justifications provided by the commenters, and various studies in deciding the appropriate test frequency. After careful consideration, BSEE determined that increasing the testing frequency to 7-days could cause increased wear-and-tear and fatigue on the equipment, without measurably increasing the reliability of the BOPs. No significant evidence was presented by supporters of a 7-day test cycle that demonstrated that more frequent testing in all situations would increase safety, and no evidence was presented for why BSEE should have a different requirement for BOP pressure tests in the Arctic than elsewhere on the OCS.

Therefore, in the final rule BSEE removed the proposed amendments that would have required operators to test their BOP systems every 7 days during Arctic OCS exploratory drilling operations. Existing regulatory provisions address similar protection concerns. Paragraph (a)(4) of § 250.737 allows for the District Manager, to require more frequent testing if conditions (Arctic or otherwise) or the BOP performance warrant. Additionally, § 250.737(d)(9) requires a function test of the annular and ram BOPs every 7 days, between pressure tests, ensuring the BOP rams will function in all operating conditions.[9]

What are the real-time monitoring requirements for Arctic OCS exploratory drilling operations? (§ 250.452)

BSEE is revising the proposed § 250.452 to clarify the operator's responsibilities for complying with the real-time monitoring (RTM) requirements.

Paragraph (a) of § 250.452 is revised by deleting the phrase "all aspects of" from the provision identifying what functions must be monitored. This revision allows the operator flexibility in determining which elements of the identified functions will be monitored. The operator is responsible for recording, storing, and transmitting data regarding the BOP system; the well fluid's handling systems on the rig; and the well's downhole conditions as monitored by a downhole sensing system, when such a system is installed. The operator will determine what functional aspects of these systems should be monitored to meet the performance requirements of this provision.

BSEE has revised paragraphs (a) and (b) of § 250.452 to make clear that it is not necessary to cease operations because of a temporary loss of the RTM data feed due to a failure or interruption in the RTM data feed to shore. In this type of situation, the operator should have the ability to gather and record the data in the control room of the offshore unit and transmit the data to shore once the data feed is restored. To clarify this, we deleted the word "immediately" from paragraph (b) of § 250.452 and added the phrase "as they are gathered, barring unforeseeable or unpreventable interruptions in transmissions," to describe the proper timing of the data transmission. Additionally, to clarify that in the event of a failure or interruption of the datalink the operator should continue collecting RTM data, we added qualifying language to paragraph (a) in § 250.452, providing that the monitoring system must be "independent, automatic, and continuous'' to ensure the operator is able to transmit data, even if not immediately, in a timely and appropriate manner.

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[9] Throughout this preamble, the Bureaus refer to regulatory provisions promulgated through the recently-finalized Blowout Preventer Systems and Well Control Rule (81 FR 25888 (April 29, 2016)) (WCR). To accommodate the respective timing of these rules, those references and the related discussions of the relevant WCR provisions are based upon the working assumption that those elements of the WCR go into effect as promulgated.

We have also revised paragraph (b) in § 250.452 by deleting the proposed text: "and who have the authority, in consultation with rig personnel, to initiate any necessary action in response to abnormal data or events." BSEE recognizes that operators typically seek to ensure that command and control decision making is primarily the responsibility of the onboard rig personnel, and that the RTM support personnel typically function in an advisory capacity. The RTM monitoring requirements seek to help improve, not disrupt, the ability of onboard rig personnel to monitor operations and assess and mitigate risks.

The final clarifying revision to paragraph (a) in § 250.452 tightens the language, changing from the proposed "you must have real-time data gathering and monitoring, capability to record, store, and transmit data" to now read: "you must gather and monitor real-time data using an independent, automatic, and continuous monitoring system capable of recording, storing, and transmitting data." Other than as discussed above, these revisions are designed to make the regulatory language clearer and easier to understand and apply.

What are the requirements for Arctic OCS source control and containment? (§ 250.471)

As discussed in Sections III.B *Approval of Alternate Procedures or Equipment* and III.D *SCCE and Relief Rig Capabilities,* BSEE is revising the language proposed in § 250.471 to clarify that operators using a MODU when drilling below or working below the surface casing must have access to SCCE that is capable of stopping or capturing the flow of an out-of-control well. Accordingly, we are revising § 250.471(a) to clearly state that the operator must have access to SCCE equipment capable of "stopping or capturing the flow of an out-of-control well". We are also adding a paragraph (i) to clarify that when an operator is requesting approval of alternate procedures or equipment to the SCCE requirements under the provisions of § 250.141, the operator must demonstrate that the proposed alternate procedures or equipment provide a level of safety and environmental protection that meets or exceeds that required by BSEE regulations, including demonstrating that the alternate procedures or equipment will be capable of stopping or capturing the flow of an out-of-control well. These revisions are in response to commenters' concerns that the language as originally proposed did not clearly state a performance standard.

What are the relief rig requirements for the Arctic OCS? (§ 250.472)

Also as discussed in Sections III.B and III.D, BSEE is revising the language proposed in § 250.472 to clarify the performance standard that must be met when proposing to use alternate equipment or procedures to the relief rig requirements of § 250.472. Specifically, we are adding the phrase "able to kill and permanently plug an out-of-control well" to the language of proposed § 250.472(a) to clearly state the performance standards the relief rig must achieve. We are also revising the language of proposed § 250.472(c) to clarify that when an operator is requesting approval of alternate procedures or equipment to the relief rig requirements under the provisions of § 250.141, the operator must demonstrate that the proposed alternate procedures or equipment provide a level of safety and environmental protection that meets or exceeds that required by BSEE regulations, including demonstrating that the alternate procedures or equipment will be able to kill and permanently plug an out-of-control well. These revisions are in response to commenters' requests for a clear statement of a performance standard and are designed to offer guidance and clarification to operators with respect to the performance-based standard established by this rule that any proposed alternate compliance must meet or exceed in connection with the requirements finalized in this rulemaking.

If I propose activities in the Alaska OCS Region, what planning information must accompany the EP? (§ 550.220)

BOEM is revising § 550.220(c)(6)(ii) to clarify the intent of the provision. This provision is designed to obtain information regarding the operator's relief rig plans through the EP. BOEM has revised the provision in response to comments, removing language that could potentially create confusion over the interaction between the BOEM EP informational provision and the BSEE operational relief rig requirements at § 250.472. The intent of § 550.220(c)(6)(ii) is to obtain the information that is known at the time of EP submission regarding the operator's plans for compliance with the requirements of § 250.472(b). Therefore, as a technical correction, we finalized the text of § 550.220(c)(6)(ii) without reference to "into zones capable of flowing liquid hydrocarbons." This revision is explained in further detail in Section IV.B.

Technical and Clarifying Edits

The Bureaus have made several additional changes between the proposed and final regulatory text that are technical made in order to clarify edits. These changes result in more easily understandable regulations but do not make substantive changes. For this reason, the Bureaus have determined that further notice and comment is unnecessary pursuant to 5 U.S.C. 553(b).

B. Discussion of and Responses to Comments

The Bureaus divided our discussion and responses to the comments received into subject matter topics, beginning with general comments, and then organized them by section number in the order in which operators would seek to comply with the regulations during permitting and operations.

Although BSEE permitting and operational requirements appear earlier in 30 CFR part 250, with the BOEM requirements following in 30 CFR part 550, in practice the IOP and EP phases governed by the 30 CFR part 550 regulations would precede the drilling approval and oversight phases governed by 30 CFR part 250. Requirements to prepare for an oil spill, which are contained in part 254, may be met at any time before handling, storing, or transporting oil in operations BSEE permits under part 250. Consequently, the subject matter topics are presented in this preamble in the following order: Definitions of *Arctic OCS* (§§ 250.105, 254.6, and 550.105) and *Arctic OCS conditions* (§§ 250.105 and 550.105), the discussion of and response to comments on BOEM's final regulations (*i.e.,* §§ 550.105, 550.200, 550.204, 550.206, and 550.220), and then the remainder of BSEE's final regulations (*i.e.,* §§ 250.105, 250.188, 250.198, 250.300, former 250.402/finalized as 250.720, 250.418, 250.447, 250.452, 250.470, 250.471, 250.472, 250.473, and 250.1920; §§ 254.6, 254.55, 254.65, 254.70, 254.80, and 254.90).

1. General Comments

Several comments addressed general concepts related to the rulemaking, instead of specific regulatory requirements proposed in the NPRM. These commenters opposed finalizing the proposed rule for a variety of reasons including: An opposition to all drilling in the Arctic Region; the proposed regulations are unnecessary, or overly restrictive or too costly; and the request for the proposed rule to be withdrawn and re-proposed with additional information. BOEM and BSEE respond to these comments below.

The U.S. Government Should Ban All Offshore Drilling in the Arctic Region

Many commenters opposed the proposed rule in its entirety because of their opposition to all drilling in the Arctic Region, based on concerns over climate change and other environmental reasons. Some of these commenters supported the development of renewable energy in lieu of continued exploration for oil and gas resources.

BOEM and BSEE strongly agree with the need to protect the Arctic environment, and the requirements of this final rule are an important means to achieve that goal. However, the decision whether or not to prevent the exploration and development in the Arctic OCS is beyond the scope of this rulemaking. OCSLA establishes a process for deciding when and where to issue leases based on a defined set of criteria (*see* 43 U.S.C. 1344). That is the appropriate process for deciding whether the Arctic OCS should be explored and developed, not this rulemaking.

Advancing renewable energy and transitioning away from reliance on fossil fuels is critical in the long term, but fossil fuels will continue to be an important part of the U.S.' energy portfolio for the foreseeable future. The Department is required by OCSLA to make the OCS "available for expeditious and orderly development, subject to environmental safeguards, in a manner which is consistent with the maintenance of competition and other national needs." 43 U.S.C. 1332(3). As discussed throughout this preamble, and in several studies and reports available in the docket, the development of the U.S. Arctic's significant resources has the potential to promote a greater national reliance on domestic energy resources, benefits for the U.S. economy, and enhanced global energy security. The protection of the Arctic marine and coastal environments where drilling activities take place is of the utmost importance to BOEM and BSEE. The requirements finalized in this rule ensure that current and future exploratory drilling activities on the Arctic OCS are conducted safely and responsibly, subject to strong operational requirements.

The Proposed Regulations Are Unnecessary or Overly Restrictive or Too Costly

A large number of commenters argue the regulations should not be finalized because they are unnecessary due to other Federal agencies' existing regulations. Many of these commenters also assert that the regulations are overly restrictive and will be too costly. The comments do not provide specific costs or identify specific offending provisions, but only that the regulations should not be finalized.

BOEM and BSEE disagree. The operating environment for exploratory drilling operations on the Arctic OCS is characterized by unique environmental conditions, geographic remoteness, and a relative lack of fixed infrastructure and existing operations. The provisions of this rule are necessary and appropriate to address those challenges.

BOEM and BSEE engaged in Government-to-Government Tribal consultations and Government-to-ANCSA Corporations consultations to discuss the subject matter of the proposed rule and solicit input in the development of the final rule. Additionally, many comments on the NPRM support the finalization of this rule. This rulemaking takes into account the feedback we have received from these consultations and public comments and the lessons learned from recent exploratory drilling activity on the Arctic OCS. The provisions of this final rule do not add significant burdens beyond those that BOEM and BSEE required of Shell in 2012 and 2015, as part of the conditions of approval for its EP and permits to drill. From inception to completion, every phase of Arctic OCS operations comes with inherent challenges and operational risks. BOEM and BSEE determined that the final rule is reasonable and necessary to ensure that Arctic OCS exploration is conducted responsibly and in accordance with the highest safety and environmental standards. The final regulations are also necessary to provide regulatory certainty to industry regarding the requirements BOEM and BSEE will continue to expect operators to meet in their exploration and drilling programs. This final rule provides greater certainty to partners and stakeholders that Arctic OCS operations will be undertaken with the utmost regard for safety and environmental protection. The estimated costs and benefits of the rule are analyzed in greater detail in the final RIA and discussed in the E.O. 12866 section.

The Proposed Regulations Should Be Withdrawn and Re-Proposed With Additional Information

Many commenters request the proposed rule be withdrawn in its entirety. These commenters request withdrawal based on two different rationales.

One group of commenters requested that BOEM and BSEE withdraw the proposed rule and re-propose a rule with provisions aligning with the recommendations from a study by the NPC, a Department of Energy Federal Advisory Committee, entitled, "Arctic Potential: Realizing the Promise of U.S. Arctic Oil and Gas Resources", (NPC Arctic Potential Study, March 27, 2015) (available at: *http://www.npcarcticpotentialreport.org/*).

We disagree with this suggestion. BOEM and BSEE participated in the development of the NPC Arctic Potential Study and used, where appropriate, knowledge gained from its development. It is our view that this final rule comprehensively addresses the challenges to prudent hydrocarbon exploration posed by the Arctic OCS's unique operating environment. BOEM and BSEE recognize the value of the NPC Arctic Potential Study as a study that considers the research and technology opportunities to enable prudent development of U.S. Arctic oil and gas resources. However, it is only one of the resources we considered in developing regulations that will ensure the safe and responsible development of petroleum resources on the Arctic OCS.

The second group of commenters recommended that BOEM and BSEE delay the finalization of this final rule until the proposed Well Control Rule was finalized.

BOEM and BSEE decided to finalize the Well Control Rule in advance of this rulemaking (*see* 81 FR 25888), although the publication of the final rule on Arctic OCS exploration in advance of the Well Control Rule would not have resulted in any conflicting provisions. Throughout both rulemaking processes, BOEM and BSEE ensured the final rule on Arctic OCS exploration and the Well Control Rule contained regulatory provisions that are consistent. The Well Control Rule applies across the entirety of the OCS, including in the Arctic OCS. Many of the provisions of the final rule on Arctic OCS exploration, however, go beyond the scope of the Well Control Rule, and respond to unique challenges posed by the Arctic OCS operating environment. Finalization of the final rule on Arctic OCS exploration, independent of the Well Control Rule, puts in place the needed systems and processes that reduce risk and provide rigorous safeguards for Alaska's North Slope coastal communities and sensitive U.S. Arctic marine environment.

2. Definitions

BOEM and BSEE proposed to add new definitions in the proper alphabetical order for *Arctic OCS* and *Arctic OCS conditions* to existing §§ 250.105 and 550.105. We received no comments on the proposed definition for *Arctic OCS conditions* and it is finalized as proposed.

BSEE further proposed to add new definitions in the proper alphabetical order for *Cap and flow system, Containment dome, District Manager, Source control and containment equipment (SCCE)* and *Capping stacks* to existing § 250.105. No comments were received to the proposed definitions at § 250.105 of *Cap and flow system, Containment dome,* or *District Manager* and they are finalized as proposed. Comments were received on the proposed § 250.105 definitions of *Arctic OCS, Source control and containment equipment (SCCE)* and *Capping Stacks.* One commenter requested the final rule include a definition for MODU.

Arctic OCS

Three commenters requested BOEM and BSEE refine the proposed definition of "Arctic OCS" in §§ 250.105 and 550.105 to include more than the Beaufort and Chukchi Sea Planning areas. Two of these commenters suggested utilizing all OCS areas north of the Arctic Circle under U.S. jurisdiction as the "Arctic OCS".

BOEM and BSEE disagree that the "Arctic OCS" should be redefined to include offshore areas beyond the Beaufort Sea and Chukchi Sea Planning Areas. We determined that the final definition in this rulemaking should align with the areas of the Arctic OCS utilized in the DOI OCS Oil and Gas Leasing Program for 2012–2017 (June 2012, available at *http://www.boem.gov/Five-Year-Program-2012-2017*). The Arctic OCS definition is reflective of the conditions and challenges the rule is designed to address, and allows focus on Planning Areas with higher hydrocarbon potential. Any other details added to this definition would increase confusion over the scope and applicability of the rule.

SCCE

One commenter stated the proposed definition of SCCE in § 250.105 excludes some of the primary intervention options, such as injection as a means to secure the well. The commenter recommended the definition for surface devices should include pumps and injection lines for dynamic kill and injection into well, and reference to subsea equipment should include jumpers, manifolds, and associated equipment to facilitate pumping into the well.

BSEE disagrees and has chosen to include as SCCE equipment only the equipment necessary to regain control of a well when the primary systems fails and that is not used in everyday drilling operations. Standard equipment (such as the BOP) is specifically excluded from the definition as it is a requirement of safe drilling operations regulated in other provisions of BSEE's rules. The definition of SCCE is not intended to be exclusive or restrictive, nor is the requirement that operators possess and have the ability to promptly deploy such equipment intended to preclude the use of other intervention mechanisms not specifically mentioned.

Capping Stacks

One commenter noted the proposed definition for capping stacks in § 250.105 limits the use of pre-positioned capping stacks to subsea wellheads when surface BOPs are used. The commenter suggests that the definition should be expanded to allow pre-positioned capping stacks to be used below subsea BOPs when deemed technically and operationally appropriate, such as with a jack-up rig.

BSEE agrees that pre-positioned capping stacks should be included in the definition. We therefore added the language "including one that is pre-positioned" to the definition for Capping Stack in § 250.105. BSEE will evaluate the use of a pre-positioned capping stack as a part of an operator's proposal on a case-by-case basis and approve their use below subsea BOPs when deemed technically and operationally appropriate, such as when an operator proposes to use a jack-up rig with surface trees.

MODU

One commenter requested a definition of MODU be included in the final rule.

BSEE disagrees. There is no one comprehensive definition of a MODU that can be utilized across parts 250, 254 and 550. MODUs include different types of vessels, including floating facilities or jack-up rigs, capable of engaging in well operations (*e.g.,* drilling, well completion and workover activities) for the purpose of exploring for or developing subsea oil, gas, or sulfur resources or related activities. What is considered a MODU may vary based on the activity being regulated. These regulations address only MODUs used for exploratory drilling, which include floating drilling vessels and jack-up rigs.

3. Additional Regulations by BOEM

Definitions (§ 550.200)

BOEM proposed to insert the acronym *IOP*—meaning Integrated Operations Plan—into the proper alphabetical location within existing § 550.200, for purposes of the IOP provisions. No comments were received on this provision and it is finalized as proposed.

When must I submit my IOP for proposed Arctic exploratory drilling operations and what must the IOP include? (§ 550.204)

BOEM proposed new § 550.204. This section requires operators to develop and submit IOPs to BOEM at least 90 days in advance of filing their EPs. The purpose of the IOP is to describe, at a strategic or conceptual level, how exploratory drilling operations will be designed, executed, and managed as an integrated endeavor from start to finish. The IOP is intended to be a concept of operations that includes a description of pertinent aspects of an operator's proposed exploratory drilling activities and supporting operations and how the operator will design and conduct its program in a manner that accounts for the challenges presented by Arctic OCS conditions. Several comments were received on this section. To clearly address the commenters' concerns, we have organized our discussion of § 550.204 in two separate topics: (i) Information requested for IOP completion, and (ii) appropriateness of IOP submission. BOEM has reviewed the comments and determined to finalize § 550.204 as proposed for the reasons stated herein.

Information Requested for IOP Completion

Many commenters generally criticized the IOP provision as being duplicative or redundant of existing requirements.

BOEM disagrees. The IOP rules are neither redundant nor duplicative of existing requirements. The IOP is meant to be an overview of all phases of the operator's proposed operations in order to allow the Federal agencies an earlier review in the planning process than currently exists. Section 550.204 requires a description of the design and operation of the proposed exploratory drilling program that demonstrates the operator is accounting for Arctic OCS conditions. Using this description, Federal agencies will coordinate and reduce potential delays by identifying possible vulnerabilities early in the planning process related to safety and environmental protection. This proactive approach enables the operator to address these issues more effectively in the EP. Though BOEM would review the IOP to ensure that the operator's submission includes each of the elements listed in § 550.204, the IOP would not require approval by DOI or the other relevant agencies. Accordingly, the IOP is fundamentally distinct from the EP. First, the provisions of OCSLA that govern the EP do not apply to the IOP in that the EP requires an agency decision while the IOP is reviewed to ensure the submission is complete. Second, the operator's IOP will contain planning information with less specificity than that furnished with the EP.

Given the important role played by contractors and the fact that many contractors hired to operate on the Alaska OCS do not have a long operating history in the region, effective contractor oversight by operators is critical, and sufficient oversight of each contractor can be a challenge. Section 550.204(f) requires operators to plan for how they will manage contractors to reduce operational risks and address the challenges associated with operations on the Arctic OCS. Further, § 550.204(b) requires operators to plan to coordinate the work of a number of contractors to ensure that time pressure or other contractor complications do not undermine safe and environmentally responsible operations. This section requires a degree of advanced planning that should identify critical paths necessary for successful operations, ensure requisite resources are allocated, and mitigates risks through adequate forethought.

Additionally, if an operator determines that information it will submit in an EP is redundant with that submitted in an IOP, § 550.201(c) provides the Regional Director discretion, on a case-by-case basis, to waive submission of required information or analyses when sufficient applicable information or analyses are readily available to BOEM. Paragraph (d) of § 550.201 also allows for referencing other pre-existing information and data when submitting an EP if that information was previously submitted or is otherwise readily available to BOEM, thus allowing the IOP to simplify the EP preparation process.

Another group of commenters asserted that information required to be included in the IOP will not always be available 90 days before the EP submission. One of the commenters explained that much of the operator's data is immature during this planning phase.

BOEM acknowledges that the IOP will be submitted at a phase of the planning process when not all details of proposed operations will be in place, and that such details will necessarily be further developed through later stages of the process. While the operator will explain how exploratory activities will be integrated in its IOP, BOEM does not expect the IOP to exhibit the same level of detail that other documents (*i.e.* EP, APD, and OSRP) contain. For example, § 550.204(f) requests the operator to list the work its contractors will perform, but does not require the operator to have selected a specific contractor at the time of IOP submission. By providing that the operator need not have finalized contractor selection, it is reasonable for the IOP to be completed, at a minimum, 90 days before the submission of the EP.

The operator should already have the information required to complete an IOP 90 days prior to submitting an EP due to the advanced planning necessary for the operator to safely operate in Arctic conditions and minimize its effects on local communities. In addition, the operator must perform detailed engineering themselves or have a contractor do such work, well in advance of the open-water season. Further, if the operator does not have the general summary information for the IOP, then it is unlikely that the operator will be in a position to submit a completed EP 90 days later.

Another of the commenters requested that BOEM provide notice to the State and local governments when it receives an IOP.

Regarding this request, we note that in addition to posting the IOP online, § 550.206(a)(2) requires the operator to submit eight copies to BOEM for public distribution. BOEM will share copies with State and local governments.

Several commenters requested clarification on whether an operator is obligated to respond to requests for additional information (RFAI) from BOEM, BSEE, or the other agencies with access to the IOP. The commenters note that if operators are obligated to respond to such requests, associated review timings should be established to ensure operators receive feedback within 45 days of submission.

The IOP will be circulated among the members in the E.O. 13580 Alaska Energy Permitting IWG, whose membership and function are discussed in Section I.B, and other relevant agencies. Members of the working group and other agencies will dialogue with the operator about any aspects of the proposed operations that may create risks. This dialogue ensures the operator is aware of elements of its proposed operations requiring clarification or revision to obtain later regulatory approvals in a manner consistent with each agency's regulatory requirements. The IOP is an informational document that must be filed and should cover the identified elements, but does not require approval by DOI. If all elements of § 550.204 are not addressed by the operator in its IOP, BOEM may request supplementation from the operator.

BOEM does not agree that the regulations should be amended to add a 45-day limit for when BOEM's feedback on the IOP should be sent to an operator after the operator has submitted its IOP. If the operator is unable to provide supplementation related to feedback given by BOEM before the end of the IOP review period, the operator would be able to furnish the material in its EP submittal. If, however, during an early point in the review period, BOEM finds that the operator's IOP is incomplete in such a way that it does not address all of the elements of § 550.204, then it may request that the operator supplement the incomplete IOP submission.

One commenter requested clarification of the need for "sufficient information" when submitting the IOP description of vessels utilized in the operator's proposed exploratory drilling program. The commenter understands this as the IOP requirement effectively establishing a 120 day review period for proposed operations (90 days for the IOP and 30 days for the EP). The commenter stated this mandatory IOP process will effectively delay EP submissions and ultimately frustrate future drilling efforts.

BOEM disagrees with the assertion that the IOP will delay the EP process, or that the IOP is designed to effectively expand that process. The final rule is a combination of prescriptive and performance-based requirements developed after extensive outreach to stakeholders, operators, and government agencies. BOEM will review the IOP for completeness, and if the agency finds that aspects of the operator's plan do not meet the necessary information obligations of § 550.204, then it will request the information be presented. The IOP is not subject to approval, and should not delay submission of the EP. Because the IOP is an overview that requires less detail than the EP, operators will be in a position to submit the IOP earlier in their planning process than the EP itself. As a result, the 90-day period will not delay the submittal of the EP.

Three commenters commented on the frequency of IOP submissions. One commenter requested clarification on whether a single IOP could address multiple EPs. Another commenter requested that BOEM consider a single IOP filed prior to an operator's first EP. The third commenter suggests the IOP be updated when an EP is updated.

BOEM disagrees that an IOP will need to be updated whenever an EP is updated. An IOP is required for each exploratory drilling program planned by an operator. However, a single IOP may cover multiple EPs when sufficient geographic and operational overlap exists. The IOP serves its primary purpose before an EP is submitted, as it informs the early planning process prior to initial EP submission. Requiring the IOP to be updated after the EP's submission would not serve any practical purpose, because the EP serves as the main point of reference for both agencies and the operator after the EP is filed.

One commenter recommended the IOP should mirror the International Association of Oil and Gas Producers (IOGP)/International Petroleum Industry Environmental Conservation Association (IPIECA) guidelines for oil spill risk assessments and management plans.[10] BOEM disagrees with this comment. The IOGP/IPIECA guidelines far exceed the expected scope of the IOP. The IOP is a conceptual document that holistically addresses an operator's Arctic OCS drilling operations from start to finish, providing regulatory agencies a preview of an operator's approach to regulatory compliance and integrated planning. The IOP does provide information on advanced preparations and staging of oil spill response assets, necessary for both BOEM's environmental impact analysis and for BSEE's overall understanding of the operator's OSRP. BOEM does not believe that the final regulations require amendment in response to these comments.

One commenter requested that IOP provisions should require proposed mitigation measures to avoid conflicts with subsistence activities. BOEM does not think this is necessary, as BOEM has determined that existing requirements address this concern. Before an EP is approved, BOEM must comply with applicable statutory requirements to analyze the potential impacts of the proposed exploration activities. As part of the analyses, BOEM analyzes how mobilization, demobilization, and exploratory drilling could affect subsistence use, resource use, and harvest activities. Both BOEM and BSEE may require additional mitigation measures at the EP and APD stages, as necessary, to address appropriately potential interference with subsistence activities. For example, because subsistence hunters are concerned that the effects of offshore oil and gas exploration might displace migrating bowhead whales and other marine mammals (like beluga whales), the Bureaus will meet with the Alaska Eskimo Whaling Commission and its whaling captains to help document traditional knowledge pertaining to bowhead whales, including movement and behavior. Given the importance of subsistence activities and related socio-cultural activities to the Alaska Native communities, operators are encouraged to work directly with interested parties to help mitigate potential impacts to subsistence activities. In addition, BOEM will continue to fund and support studies to better understand the potential impacts from OCS operations on marine mammals and subsistence activities.

One commenter asserted that the proposed rule failed to address public and private investment in on-shore infrastructure supporting oil spill response and protection of specific lands and resources. The commenter noted that the proposed rule neglected local community involvement in oil spill response capabilities, especially at Point Lay, the local community most likely to be impacted by the oil spill response activities. The commenter suggested that regulation be written to specifically require onshore infrastructure development at Point Lay and Cape Sabine, both former Distant Early Warning Line radar sites with existing, but unutilized infrastructure. The commenter shared his Kali traditional knowledge of local meteorological conditions with BOEM and BSEE personnel and has noted that weather conditions often times permit safe flight operations from Point Lay when they are suspended in Barrow and Wainwright.

BOEM has determined that both existing regulations and regulations finalized in this rulemaking address the commenter's concern regarding community involvement. Section 550.202 mandates that operators plan and prepare to conduct their proposed activity safely in conformance with all applicable legal requirements and sound conservation practices in a manner which neither unreasonably interferes with other OCS uses nor causes undue or serious harm to the human, marine or coastal environment. Additionally, § 550.204(j) requires the operator to include in its IOP a description of whether and to what extent a project will rely on local community workforce and spill cleanup response capacity. Regarding the request for specific onshore infrastructure investments, BOEM cannot in this rulemaking specify the location of such investments.

Two commenters assert that introducing an IOP prior to the EP is impractical and unnecessary in terms of timing and objectives. One commenter recommended the submittal of the EP should continue to precede the IOP to allow timely exploration to occur while the IOP is being developed. The commenter argued there is a lack of efficiency in asking operators to prepare a complete IOP as a pre-requisite to engaging in meaningful project-related dialogue and that early engagement between operators and the Federal agencies would be more meaningful as an iterative pre-application process that feeds into the IOP. The second commenter proposes the removal of the IOP as a separate document and that the EP and APD processes are adapted and clarified to meet the intentions of the IOP requirement.

BOEM disagrees and has determined to finalize the IOP provisions as proposed. The IOP requirement calls for information that is different from what is required to be provided in an EP or an APD. Information in an IOP contains a different level of detail and is required at a different point in the planning process. By requiring an IOP, the entire planning process should become more efficient by decreasing the likelihood of requests for additional information or plan modifications during the later stages that require approval. The early engagement facilitated by the IOP requirements of § 550.204 should increase efficiency by improving communication between agencies and operators, improving early agency understanding of and operator preparedness for planning activities.

Appropriateness of IOP Submission

Several commenters assert that the requirement to submit an IOP 90 days before submitting an EP for Arctic exploratory drilling operations is inconsistent with the OCSLA requirements at 43 U.S.C. 1340(c), and the Department is improperly exceeding its jurisdiction by requiring submission of the IOP information. Two of the commenters also assert that the IOP would require reporting of information and data beyond DOI's scope of jurisdiction and is not based in any statutory authority granted by Congress.

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[10] The International Association of Oil and Gas Producers (IOGP) is an association, formed in 1974, whose members include public, private, and state-owned oil and gas companies and upstream service companies. The International Petroleum Industry Environmental Conservation Association (IPIECA), formed in 1974, is a global oil and gas association addressing environmental and social issues.

BOEM disagrees. The OCSLA requires the submission and approval of an EP, but does not specify or restrict what other information BOEM may require before the EP is submitted. The OCSLA provides the Secretary authority to require information described in the IOP. Section 1334(a) of Title 43 of the U.S.C. grants the Secretary authority to "prescribe and amend such rules and regulations as [s]he determines to be necessary and proper in order to provide for the prevention of waste and conservation of the natural resources of the [OCS]." Section 1332(6) declares that: "operations in the [OCS] should be conducted in a safe manner by well-trained personnel using technology, precautions, and techniques sufficient to prevent or minimize the likelihood of blowouts, loss of well control, fires, spillage, physical obstruction to other users of the waters or subsoil and seabed, or other occurrences which may cause damage to the environment or to property, or endanger life or health."[11]

Section 1348 of Title 43 of the U.S.C. imposes a duty on lessees and operators to "maintain all operations . . . in compliance with regulations intended to protect persons, property, and the environment on the [OCS]."[12] The ability of lessees to explore for oil and gas on the Arctic OCS in accordance with these statutory mandates depends on early, integrated planning. This planning necessarily implicates activities, such as the operation of vessels which are regulated by other Federal agencies but also inform and influence the Department's oversight functions. For example, while the Department does not directly regulate the operations of vessels carrying capping stacks to Arctic well-sites, ice-management vessels or vessels responsible for towing rigs, lessees cannot safely conduct exploratory drilling without properly planning for these activities. Such activities can result in damage to operational equipment critical to DOI-regulated drilling activities, which can in turn compromise, reduce, or force modifications to approved operational or safety capabilities and equipment. Similarly, they can give rise to changes to approved operational schedules, which in the Arctic are particularly critical in light of the limited open water season, the timing of recession and encroachment of sea ice at drill sites, marine mammal migrations, and subsistence hunting seasons, among other considerations.

The EP and the IOP serve different purposes and are not governed by the same provisions of OCSLA. The EP is a statutorily mandated submission under 43 U.S.C. 1340(c), approval of which is required prior to exploration of any OCS lease. BOEM regulations set forth comprehensive and detailed requirements for the contents of an EP.[13] BOEM carefully scrutinizes submitted EPs to ensure that they satisfy all applicable requirements, are consistent with lease terms and governing law, and would not cause serious harm or damage to life, property, any mineral, national security or defense, or the marine coastal or human environment.[14] EPs also provide the basis for analyses and determinations required by other Federal laws, as well as subsequent BSEE review and approval of APDs. Upon satisfaction of all applicable requirements, BOEM approves an EP, often subject to conditions; the terms of that approval are binding and govern activities conducted pursuant to the EP.

The IOP is fundamentally distinct from the EP, and does not implicate the section of OCSLA that governs EPs, 43 U.S.C. 1340. The IOP will be required to be submitted to BOEM well in advance of the EP, at a time when the Department recognizes the operator might not possess the type of detailed and specific information that is required to obtain approval of an EP. It requires Arctic-focused conceptual planning information to encourage and facilitate the development of integrated operational strategies early in the planning process. While the IOP will be reviewed to ensure that the submission is complete, addressing each of the elements listed, the IOP is not subject to approval by any Federal agency and does not bind the operator's future activities. Rather, the IOP, unlike the EP, is designed to be a preliminary informational resource to facilitate relevant Federal agencies' early familiarity with, and opportunities for constructive feedback on, important concepts related to the design of an operator's planned exploration program in an integrated manner that accounts for the unique Arctic OCS conditions. This process has the potential to facilitate the later EP review, but it is fundamentally distinct from the EP itself.

Agency regulations have long recognized the need to obtain through the planning process information about activities outside of the Department's direct regulatory jurisdiction but which are clearly relevant to approval of operations within our jurisdiction.[15] OCSLA provides the Secretary with the authority to require information necessary to ensure that Arctic OCS operations are safe and environmentally responsible and to help facilitate early review by the Department and other agencies in advance of the EP. 43 U.S.C. 1334(a). The IOP requirement reflects a reasonable exercise of that authority.

Section 1340(c) of OCSLA requires lessees to submit an EP for approval before they commence exploration pursuant to their lease, and it requires BOEM to take action on an EP within 30 days after submission.[16] The 30-day time limit for reviewing an EP begins only after BOEM's Regional Supervisor deems the EP submitted.[17] This statutorily mandated regulatory requirement is specific to EPs and does not affect the authority in OCSLA to require the preliminary informational submission of the IOP.

One commenter argued that industry should not have to incur the additional cost of an IOP considering the roughly 124 day drilling window in the Chukchi Sea, and that the 90 days could instead be spent by agencies to integrate their services for regulatory efficiency. The commenter asserted that agencies must start working together to streamline the regulatory process, to fund and support Arctic-centric science, and to support infrastructure development in this remote region of the country.

We agree with the commenter's concern for agency integration and note the key purpose of the IOP is to facilitate interagency coordination on matters of mutual interest. The regulatory oversight of the Arctic OCS is shared by many agencies and the need for integration among them is recognized by the establishment of the E.O. 13580 Alaska Energy Permitting IWG. The E.O. 13580 Alaska Energy Permitting IWG consists of representatives from Federal agencies which include DOI, the Departments of Defense, Commerce, Agriculture, Energy, Homeland Security, and the EPA. BOEM will circulate the IOP amongst the aforementioned agencies;

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[11] *Id.* at section 1332(6).

[12] *Id.* at section 1348(b)(2).

[13] *See* 30 CFR 550.211 through 550.228.

[14] *Id.* at §§ 550.202, 550.233.

[15] *See, e.g.,* § 550.224 (requiring description in EP of the support vessels, offshore vehicles, and aircrafts you will use to support your exploration activities, including maps of travel routes and methods for transportation of fluids, chemicals, and wastes); § 550.257 (same for Development and Production Plans (DPPs) and Development Operations Coordination Documents (DOCDs)); § 550.225 (requiring description in EP of onshore support facilities to be used to provide supply and service support for the proposed exploration activities); § 550.258 (same for DPPs and DOCDs).

[16] 43 U.S.C. 1340(c).

[17] *See* 30 CFR 550.233.

such circulation and familiarity will result in a more collaborative effort in regulating OCS oil and gas exploration. With respect to the commenter's concerns regarding timing, the requirement to submit the IOP should not impact the length of the available drilling season as the IOP may be submitted well in advance of the open-water season. With respect to costs, those issues are analyzed at greater length in the final RIA. However, we note here that the type of planning reflected in the IOP is essential for the successful execution of any Arctic OCS exploratory drilling campaign, so the only costs associated with the requirement should be the limited costs of assembling those plans for submission.

How do I submit the IOP, EP, DPP, or DOCD? (§ 550.206)

BOEM proposed to revise § 550.206 to include information that explains how operators should submit their IOPs and allowing operators to request the nondisclosure of information in the IOP using established DOI processes. As is currently the case with EPs, Development and Production Plans (DPPs), and Development Operations Coordination Documents (DOCDs), operators requesting the nondisclosure of portions of an IOP should provide BOEM with two separate versions of the IOP; a public version from which potentially exempt information is redacted, and an agency version with such information present, but clearly marked as proprietary.

Several comments were received on this section. BOEM has evaluated these comments and decided to finalize § 550.206 as proposed. Two commenters requested that BOEM require planning information be submitted electronically to allow immediate availability for public access. This requirement would allow BOEM to immediately upload public-information copies of EPs and IOPs without the intermediate step of reformatting the operator's submissions.

We determined electronic submittal should remain optional. Currently, DOI allows electronic submittals of all or part of the EP and the final rule will allow electronic submission of all or a portion of the IOP. Whether the information is received electronically or in the form of a hardcopy, BOEM will post the appropriate information on *http://www.boem.gov/alaska-region/*. If documents are not received electronically, BOEM will take the necessary steps to convert the files to a format compatible for online viewing by the public.

One commenter recommended that EP requirements be updated to require liaison with DOI as soon as the planning process starts, in order to coordinate forward planning and keep authorities abreast of the approach and milestones related to the EP. The commenter recommended the regulations be revised to require the EP scope be reviewed to ensure that it includes appropriate information requirements related to planning of integrated operations and how this will be achieved. The commenter goes on to recommend that these issues will be discussed as part of the overall EP development process, and that the APD scope be reviewed to ensure that it includes specific requirements for documentation of planned integrated operations, including finalized vessels, contractors and associated management systems. The commenter stated that by establishing such an approach, along the lines of approaches taken by the United Kingdom, Norway, Australia and others, the process for documenting selection and suitability of a rig would be simplified, enabling focus on other risk elements relating to how the unit will be utilized in integrated operations.

BOEM has determined the commenter's recommendations are addressed in the finalized provisions at § 550.204. Compliance with the provisions of § 550.204, related to the submission of the IOP, allows for operators and DOI to coordinate early in the planning process, and allows early visibility and opportunities to address how an operator's activities will be conducted in an integrated manner.

One commenter requested to receive a copy of all Arctic OCS applications and be provided with at least 30 days to review and comment on the applications.

BOEM's existing regulations allow for the public to review and, as appropriate, allow for comment from State, municipal and tribal governments. As stated in the NPRM, BOEM intends to post public versions of IOPs to its Web site upon receipt. Once an EP or DPP is deemed submitted, it is posted on BOEM's Web site, *http://www.boem.gov/alaska-region*. Additionally, § 550.232, *What actions will BOEM take after the EP is deemed submitted?*, allows the Governor of each affected State 21 calendar days to submit comments. During this time, BOEM will make the EP available for public review and comment. Section 550.267, *What actions will BOEM take after the DPP or DOCD is deemed submitted?*, provides that BOEM will make the DPP publicly available within 2 business days of deeming it submitted and accept comments for 60 days after making it available to the public. BOEM has determined these efforts toward public engagement are adequate. BOEM also notes that, particularly with respect to EPs, additional time for public engagement is statutorily constrained.

One commenter recommended that DOI conduct timely and meaningful consultation with Alaska Native tribes before approving an EP. BOEM agrees. Consistent with E.O. 13175 (Consultation and Coordination with Indian Tribal Governments) and Secretarial Order 3317, BOEM requests Government-to-Government consultation with Alaska Native tribes for which the exploration activities could have tribal implications. The Department is committed to fulfilling its tribal consultation obligations, whether directed by statute or administrative action such as E.O. 13175, or other applicable Secretarial orders or policies.

One commenter requested clarification in the final regulations that evidence of equipment ownership or contracts with equipment providers is required only for an APD, but not required for approval of an EP or an OSRP. The commenter expressed concern with having to make commercial commitments to very expensive equipment contracts before getting confirmation from the Bureaus that the plans based on that equipment would be approved. The commenter stated there is sufficient time after EP and OSRP approval for the operator to procure equipment that conforms to the approved plan, and to provide evidence of such procurement at the APD stage.

BOEM does not believe that the final regulations require amendment in response to this comment. Both existing regulations and this final rule require varying levels of information about operator safety and oversight management at progressive stages of the planning and approval process. This information would begin with general information and narrow down to increasing levels of detail with successive regulatory submittals, as the project proceeds from planning to implementation. For example, at the IOP stage, we recognize that operators may not have contracts for vessels finalized or precise dates of drilling so, accordingly, specific names of contractors are not necessary, but could be provided if available. At the EP stage, § 550.220(c) requires, among other planning information, a preliminary general description of SCCE and relief rig capabilities needed for compliance with §§ 250.471 and 250.472. BOEM anticipates that the relief rig description may be general at the EP stage, but detailed enough for BOEM to confirm that the operator has plans in place for how it would conduct its operations safely and in compliance with the regulations. Further, existing regulation § 550.211(c) requires that a description of the drilling unit and associated equipment be provided in the EP along with a brief description of its safety and pollution prevention features, type of fuel, and an estimate of the maximum quantity of oils, fuels and lubricants. Existing regulation § 550.224(a) also requires at a general level a description of crew boats, supply boats, anchor handling vessels, ice management vessels, aircraft, and other vessels. These longstanding requirements, as supplemented by this rule, lay out a clear picture of the type and level of detail required at different stages of the approval process that is both achievable and appropriate for the management of these operations.

If I propose activities in the Alaska OCS Region, what planning information must accompany the EP? (§ 550.220)

BOEM proposed to revise several of the existing provisions at § 550.220 to ensure, through thorough advanced planning, that operators are capable of operating safely in the extreme and challenging conditions of the Arctic OCS. Revisions to the section include amending the existing "Emergency Plans" provision at § 550.220(a) to add fire, explosion, personnel evacuation, and loss of well control to the events for which emergency plans are required, and to replace the terms "blowout" with "loss of well control" and "craft" with "vessel, offshore vehicle, or aircraft" for clarification purposes. Finally, BOEM proposed creating a new § 550.220(c), which would set forth additional information requirements for EPs that are proposing exploration activities on the Arctic OCS.

Several comments were received on the provisions in this section. BOEM has reviewed the comments and determined to finalize § 550.220 as proposed for the reasons stated herein. One technical revision is finalized at § 550.220(c)(6)(ii). As discussed above in Section IV.A, this revision is required to correctly align the provision with the relief rig planning requirements of § 250.472. For a full discussion of the comment and our response, see the discussion of § 250.472 in Section IV.B.

Two commenters recommend that the end of season date should be decided by the regulators and not by the operators, and also that the operator should only be allowed to drill into hydrocarbon zones with enough time to complete a relief well and remove oil before the freeze-up date. One commenter expressed concern that the operator may overstate their relief well capabilities in order to maximize the length of their drilling season.

BOEM agrees with the commenters. To clarify, the end of season dates that the operator proposes in its EP are anticipated dates. BOEM, in consultation with the NWS, will analyze past and present meteorological conditions, oceanic conditions, and sea ice concentration and movement to determine if the operator has provided an appropriate end of season date estimate to account for its own unique operational capabilities and limits. BOEM does this through the establishment of the trigger date, or estimated seasonal ice encroachment date, that sets a deadline on when the operator can drill or work on the surface casing, so that risks associated with late season drilling are addressed and response and cleanup activities can occur in a timely manner.

Two commenters strongly supported the imposition of an end of season date for operators and request removal of the word "anticipated" in § 550.220(c)(6) to ensure that Arctic OCS operators provide a firm date for their end of seasonal operations to avoid increased risks associated with freeze-up. The commenters further recommended that the final rule provide the Bureaus authority to require operations to terminate before these dates if actual conditions during the drilling season indicate earlier likelihood of ice encroachment over the drill site. The commenters suggest these dates should undergo scientific review by the relevant agencies and should be based on at least ten years of historical ice and weather data.

BOEM disagrees with removing the word "anticipated" from the provisions of § 550.220(c)(6). There are two dates an operator must address in this provision when onsite operations will be complete and when drilling operations will terminate. These dates retain some flexibility at the EP stage, as they are based on a number of predictive factors related to the operator's capabilities to mitigate risk in operating on the Arctic OCS and to the prevailing meteorological and oceanic conditions that vary from year to year. Many of the provisions finalized in this rulemaking require the operator to provide BOEM and BSEE pertinent information that may require exploratory drilling operations to terminate at an earlier date than anticipated at the EP stage. For example, § 250.188 requires the operator to report to BSEE information on various incidents, including sea ice movement that may affect operations or trigger ice management activities and any unexpected "kicks" or operational issues that could result in the loss of well control. We further note the anticipated end of season dates are reviewed through interagency and scientific review prior to an approval of an EP.

Two commenters recommended adding to the final rule a provision requiring operators to develop, as part of the EP, a detailed written Oil Spill Prevention Program that includes a training program. One of the commenters suggest the prevention plan should address critical oil spill prevention programs such as blowout preventer testing, well control, corrosion monitoring and control programs, maintenance and testing of leak detection systems and alarms, and other prevention work.

BOEM and BSEE disagree. Oil spill prevention is a common theme among BOEM and BSEE regulations with the end goal being to prevent serious harm or damage to life, property, any mineral, national security or defense, or the marine, coastal or human environment. As planning is an essential part of spill prevention, the finalized provisions at § 550.220(a) mandate that the operator describe its emergency plans for responding to a variety of incidents, including a loss of well control, at the EP stage. Similar requirements at existing § 550.213(g) require the operator to discuss its worst-case blowout scenario in the EP, including options for response, such as surface intervention and a relief well. Further, existing regulations at § 550.219 mandate that the operator submit an OSRP in accordance with BSEE requirements in part 254, including the training requirements set forth in § 254.29. Accordingly, the Bureaus do not believe that the proposed revisions to § 550.220 are necessary or appropriate.

One commenter recommended deleting § 550.220(a) as existing regulations require a description of plans in the event of a loss of well control, the loss or disablement of a drilling unit, and the loss or damage to support craft, and the proposed language requires information concerning emergency plans in the event of 'fire, explosion, or personnel evacuation'. The commenter explains that this information is currently captured by Emergency Evacuation Plans drafted for each of its drilling units and submitted to the U.S. Coast Guard (USCG) pursuant to 33 CFR 146.210. The commenter requested

BOEM incorporate these documents by reference and not require the information to be submitted multiple times across agencies.

BOEM disagrees. Drilling operations, especially in the Arctic OCS, are subject to operational risks and environmental challenges during every phase of the endeavor. For the most part, the text of § 550.220(a) remains unchanged from longstanding requirements. To the extent that operators have compiled the relevant information for other purposes, the burdens of providing them for the EP are minimal and may potentially be addressed through reference on a case by case basis.

One commenter stated the information requested in § 550.220(c)(1) is unnecessary and repetitive, as existing § 550.211 already requires a detailed description of drilling activities and this same information is also requested as part of the IOP under § 550.204.

BOEM disagrees that § 550.220(c)(1) is unnecessary and repetitive, as existing § 550.211 sets forth general requirements for what must be included with an operator's EP anywhere on the OCS. Because of the unique operating environment of the Arctic OCS, proposed activities in this region are subject to additional levels of scrutiny and specialized requirements. Section 550.220(c)(1) is addressed directly to that need, calling for descriptions of the suitability of proposed operations for Arctic OCS conditions, in contrast to the more generic requirements of § 550.211. Additionally, as explained in previous responses to comments, the operator's plans furnished with the IOP are less detailed than the information later available and required for submission with the EP, providing an opportunity for elaboration based on new information as it comes available.

One commenter is supportive of resource sharing with other operators, provided that appropriate terms and agreements can be made. However, the commenter asserted the requirement to share these proprietary private-party agreements under § 550.220(c)(5) is not appropriate and opposes the attempt to regulate what resources will be shared and with whom. The commenter asserted that involvement in any resource sharing agreements will not affect the operator's ability to meet the regulatory requirements regarding oil spills and emergency planning.

BOEM disagrees with the commenter's characterization of the regulation and clarifies that § 550.220(c)(5) is not an attempt to mandate resource sharing by regulation. Instead, this is a requirement to inform BOEM about any agreement the operator may have with a third party for sharing of assets or provisions for mutual aid in the event of an oil spill, as applicable, so regulators are aware of what response resources are available to an operator in the event of a loss of well control. This information is critical to ensure that the operator has made the necessary arrangements to respond appropriately in the event of a loss of well control incident. This information is also critical to confirm the operator's compliance with the relevant regulatory requirements related to well control equipment. To the extent that operators rely on such arrangements to satisfy their regulatory obligations, it is essential for the Bureaus to have access to the terms and conditions of those arrangements to confirm compliance. Additionally, the operator is required under this final rule at § 250.470(f)(1) and (3) to demonstrate at the APD stage that its membership agreements with cooperatives, service providers or other contractors include 24-hour per day availability of SCCE or related supplies while it is drilling or working below the surface casing. The operator is also required to describe its or its contractor's ability to access or deploy all necessary SCCE in accordance with § 250.471 and the SCCE listed in its EP. It is the operator's responsibility to ensure that reliance on resource sharing arrangements does not compromise its ability to fully and promptly respond to an event, and the required information is important to the bureaus' ability to ensure that this is addressed. We note that proprietary information is protected in accordance with existing §§ 250.197 and 550.197, *Data and information to be made available to the public or for limited inspection.*

One commenter asserted that the anticipated end of season dates as described in § 550.220(c)(6) should not be driven by a specific calendar date, but by the application of performance-based principles including the ability of the operator's equipment, procedures, and expertise to effectively manage and mitigate risks that are reasonably likely to occur.

BOEM notes that the end of season dates discussed in the final rule at § 550.220(c)(6) are developed largely based on the capability of the operator's equipment and procedures to manage and mitigate risks associated with Arctic OCS conditions. Any date established depends on a number of factors, including a trigger date set by the Bureaus based on an evaluation of earliest sea ice encroachment, the latest ice and weather forecasts, the prevailing meteorological and oceanic conditions, and the timeframe in which an operator could drill a relief well. The specific calendar date is calculated using a performance-based metric, allowing for the operator to apply its capabilities and expertise in reaching a specific date, as approved by the Bureaus.

One commenter recommended deleting the entirety of § 550.220(a), (c)(3), and (c)(4) and replacing them with more performance-based requirements. Specifically, the commenter suggests that the EP be required to contain general planning information on source control and containment capabilities, including anticipated location and mobilization/demobilization times of equipment to mitigate risk from a loss of well control incident.

BOEM disagrees and is finalizing these sections as proposed. One of the main goals of this rulemaking is to help ensure, through advanced planning, that operators are capable of operating safely in the extreme and challenging Arctic OCS conditions. This rulemaking amends existing § 550.220(a) to add fire, explosion, and personnel evacuation to the events for which emergency plans are required and to replace the terms "blowout" with "loss of well control" and "craft" with "vessel, offshore vehicle, or aircraft" for clarification purposes. Paragraph (a) of § 550.220 otherwise remains unchanged from its longstanding form, and keeps the development of emergency plans largely within the performance-based control of the operator. Paragraphs (c)(3) and (4) of § 550.220 simply require the operator to provide a general description in its EP of how it plans to satisfy the separate operational requirements imposed by BSEE at §§ 250.471 and 250.472. While the operator has flexibility in determining how it will comply with those requirements, making the required EP description of the operator's compliance plans more general or performance-based would be unnecessary and inappropriate, and would not satisfy the Bureaus' need to ensure appropriate planning for compliance with the regulations.

One commenter requested that the requirement to provide some data for the APD be accelerated to the EP, including more information to account for operations in Arctic OCS conditions; more detail on emergency and critical operation curtailment plans; a detailed description of how the drilling rig, relief well rig, SCCE, support vessels and other associated support equipment and activities will be designed and conducted in a manner that accounts for Arctic OCS conditions; and information regarding operators' capabilities for preventing, controlling and/or containing a WCD. The commenter also recommended the IOP be included in the EP application as an appendix and be subject to public review and comment.

Both existing regulations and the regulations finalized in this rulemaking require varying levels of information at progressive stages of the planning and approval process. Furthermore, this final rule contains a combination of prescriptive and performance-based requirements that address a number of important issues. The required submissions begin with general information and are followed by more specificity with successive regulatory submittals, as the project proceeds from planning to implementation. The IOP is an overarching, high-level description of the integration of the exploration activities that provides an advanced summary of all phases of the proposed operations for the relevant Federal agencies to review and is designed to enable Federal agencies to identify possible vulnerabilities early in planning, and to facilitate interagency communication and discussion about possible permitting issues before submission of the EP. At the IOP stage, operators may not have contracts for vessels finalized or precise dates of drilling, accordingly, specific names of contractors are not necessary, but could be provided. At the EP stage the operator must provide a general description of its SCCE capabilities and relief rig plans, in accordance with § 550.220(c), conforming to §§ 250.471 and 250.472. BOEM anticipates that the relief rig description may still be general at the EP stage, but will be detailed enough for BOEM to confirm that the operator has plans in place for how it will conduct operations safely in compliance with the regulations. Existing § 550.213(g) also requires that an EP include a blowout scenario addressing matters including surface intervention and relief well capabilities. Section 550.220(c)(1) requires the EP to provide a description of how an operator will design and conduct the proposed activities in a manner that accounts for Arctic OCS conditions; including a description of how the operator will manage and oversee those activities as an integrated endeavor. Additionally, § 550.220(a) requires that the operator submit a description of emergency plans describing the operator's ability to respond to a fire, explosion, personnel evacuation, or loss of well control, as well as a loss or disablement of a drilling unit, and loss of or damage to a support vessel, offshore vehicle, or aircraft with the EP. These new and existing provisions provide for the appropriate level of detail regarding an operator's plans at successive stages of the approval process. In response to the comment recommending that the IOP be included as an appendix to the EP application, BOEM will have received the operator's IOP at a minimum of 90 days before the EP submittal; therefore it is optional for the operator to include the IOP as an appendix in the EP. In response to the commenter's recommendation of having the public review and comment on the IOP, BOEM will post public versions of the operator's IOP to its Web site when received.

One commenter suggested requiring that drilling rigs not previously used in frontier areas, such as the Arctic OCS, undergo a mandatory third-party review of the unit's design and that such review be submitted as part of the EP application.

BOEM does not believe that the final regulations require amendment in response to this comment. The information provided with the operator's EP is general by necessity; more detailed information becomes available as the operator progresses through the planning process. In accordance with existing § 550.211(c), the EP must include a description of the drilling unit. Later in the planning process at the APD stage, under finalized § 250.470, BSEE requires the operator to submit specific information on the drilling unit. This includes information required in finalized paragraphs (a)(2) and (g) of § 250.470, such as detailed descriptions of how the drilling unit will be prepared for service on the Arctic OCS and how the operator will comply with the requirements of API RP 2N, *Recommended Practice for Planning, Designing, and Constructing Structures and Pipelines for Arctic Conditions,* Third Edition. The finalized requirements at § 250.473(a) mandate that all operators operating on the Arctic OCS use only equipment or materials that are rated or de-rated for service conditions that can be reasonably expected during operations.

Additionally, the operator's SEMS and the accompanying audit performed by a third-party must address the mechanical integrity of critical equipment. The revised requirements at § 250.1920(b)(5) will require Arctic OCS operators to increase their SEMS auditing frequency from every three years after the initial audit to every year in which drilling in the Arctic is conducted. Existing § 250.1920 requires that a third party Audit Service Provider accredited by a BSEE-approved accreditation body perform the audit. Accordingly, the proposed revisions are not necessary.

Two commenters recommend expanding the EP to address additional information including: Evidence that the operator consulted with marine mammal co-management organizations; a description of steps the operator will take to mitigate subsistence impacts, the establishment of appropriate start and stop timing for operations to minimize any potential conflict with subsistence activities, and an approved Conflict Avoidance Agreement (CAA) between the operator and the Alaska Eskimo Whaling Commission (AEWC). One of the commenters further recommended if a CAA is not included, then the EP should include an explanation as to the consultation process.

BOEM appreciates the commenter's concern for mitigating subsistence impacts and does not believe that the final regulations require amendment in response to this comment. For example, § 550.227 requires the operator to, among other things, assess the potential impacts of its proposed exploration activities, describe resources, conditions, and activities that could be affected by exploration operations (including impacts to marine mammals and subsistence and harvest practices), and list the agencies and persons that it consulted with regarding potential impacts associated with proposed exploration activities. Section 550.204(i) requires a description of the operator's efforts to minimize impacts on local community infrastructure. BOEM will also analyze subsistence impacts through its NEPA analyses.

With regard to the CAA processes, BOEM's Alaska OCS Region has regularly noted their positive value in public forums. The CAA is an agreement between AEWC and the operator and is considered a private agreement. As such, it is outside the scope of these regulations to require an operator to obtain a CAA from another entity. Although there is not a requirement for a CAA, discussion of resolutions during the consultation process and plans for continued consultation are required to be included in the EP. BOEM and BSEE continue to be committed to engaging on a routine basis with the AEWC. The AEWC leaders and members bring unmatched perspectives and insights into the relationships that BOEM and BSEE seek to maintain. With respect to the commenters suggestion that the operator be required to include evidence that the operator consulted with marine mammal co-management organizations, § 550.222 addresses the commenters concerns. Section 550.222 requires the operator to include in its EP a description of the measures it took, or will take, to satisfy conditions of lease stipulations related to its proposed exploration activities. Because a lease stipulation can be formulated in collaboration with a co-management organization at the lease sale stage, evidence of how the operator satisfied the conditions of the lease sale stipulation must be included in the EP.

4. Additional Regulations by BSEE

What incidents must I report to BSEE and when must I report them? (§ 250.188)

The existing regulations at § 250.188 require operators to provide oral and written notification to the BSEE District Manager (who in the Alaska OCS region is the Regional Supervisor) of, among other things, any injuries, fatalities, losses of well control, fires and explosions, and incidents affecting operations. BSEE proposed to add a new paragraph (c) to this section requiring operators on the Arctic OCS to provide an immediate oral report to the BSEE onsite inspector, if one is present, or to the Regional Supervisor, of any sea ice movement or condition that has the potential to affect operations or trigger ice management activities, as well as to report the start and termination of these activities, and any "kicks" or operational issues that are unexpected and could result in the loss of well control. The new provision would likewise require a written report of ice management activities within 24 hours of their completion.

Several comments were received on this section. BSEE has evaluated these comments and decided to finalize § 250.188(c) as proposed. We have separated comments received on this section into two topics: (i) Comments on ice management reporting, and (ii) comments on reporting of kicks or operational issues that are unexpected and could result in the loss of well control.

Ice Management Reporting

Two commenters assert that the ice management reporting requirements are too subjective and vague, and that the reporting should be limited to ice incursion incidents that affect operations or trigger ice management activities as stated in the ice management plan. One of these commenters further asserted that the requirement would necessitate nearly constant communication with BSEE regarding sea ice movement and conditions, and requested that BSEE allow 24 hours to report the incident so the operator is able to focus on a safe response to the incident before contacting the regulator.

BSEE disagrees with these comments. The ice management reporting requirements of this provision require operators to remain in close communication with BSEE about sea ice conditions that have the potential to affect operations before they reach the point of triggering ice management activities as stated in the ice management plan. This requirement does not necessitate constant communication, as the reporting requirements are limited to sea ice movements or conditions that have the potential to affect operations or trigger ice management activities. Just as the operator needs to have sufficient time to plan and act in the event that ice poses an operational hazard, BSEE would need sufficient time to oversee the safety of an operator's reactions and prepare to respond, if a response is necessary, due to a safety or environmental incident resulting from an ice event. BSEE does not agree that the identified standard is vague or ambiguous, and is confident, including based upon recent experience in 2012 and 2015, that Arctic OCS operators will be able to implement the provision in practice, and in coordination with the BSEE inspector or Regional Supervisor.

The requirement to notify the BSEE inspector on location or the Regional Supervisor of sea ice movement or conditions that have the potential to affect an operation or trigger ice management activities is important and appropriate. BSEE agrees with the commenter's statement that the operator should focus on a safe response to an active incident, but we disagree with the commenter's request to allow 24 hours to report an incident. The requirement for an immediate oral report is satisfied by notifying the onsite inspector or BSEE Regional Supervisor when an event or potential event is recognized. Requiring an immediate oral report is reasonable and likely will not burden the operator. This requirement will ensure that BSEE is informed of ice management concerns but will allow the operator to focus on executing safe ice management operations. Consistent with the prioritization of safe ice management operations, the regulation allows 24 hours for the written report to be completed.

One commenter questioned the suitability of § 250.190, *Reporting requirements for incidents requiring written notification,* for use with the ice management reporting required by proposed § 250.188(c)(2), particularly in the case where there is no damage or injury. BSEE determined the information requested in § 250.190 is generally appropriate for these purposes, as all the information required may be relevant to reporting ice management activities in certain circumstances. The person completing the report has the option to state that specific information is not applicable (*e.g.,* no damage or injury occurred).

Two commenters suggested the ice monitoring requirement should be implemented to focus on the operators specifying reporting requirements in advance, based on the risks of a particular location, and these risks should be included in the ice management plan.

BSEE agrees in part. The operator is responsible for addressing the particular ice event, based on the ice management plan submitted to BOEM under § 550.220(c)(2). The operator's ice management plan should address how the operator will respond to and manage ice hazards, its ice alert procedures, and the procedures and thresholds for activating the ice management system. This ice management plan is required as part of the EP, which BOEM reviews to ensure the plan addresses all of BOEM's requirements. However, BSEE also believes that it is necessary and appropriate to establish baseline reporting requirements, not subject to individual operator plan specifications, to enable the agency to perform its necessary oversight functions, and therefore that no revision to the rule is needed in response to the comment.

One commenter proposes revising § 250.188(c)(1)(i) by deleting the requirement to report any sea ice movement or condition that has the potential to trigger ice management activities. The commenter suggests that compliance with these requirements would be achieved by including BSEE on the notification list used when an ice alert code is changed. BSEE does not agree that § 250.188(c)(1)(i) needs to be revised. The language of that provision makes it clear when the operator needs to notify BSEE. The commenter's suggested revision would change the mandatory reporting requirement to a provision allowing the operator to define its notification obligations through its ice management plan. Furthermore, it is the responsibility of the operator to determine how to comply with its notification obligations, including through use of its ice alert system.

Kick Reporting

Two commenters objected to the requirement to notify BSEE immediately of a kick or an unexpected operational issue that could result in a loss of well control, as the operator should only focus on making conditions safe at the well site and this provision would take the operator's focus away from securing the well. One of the commenters recommended BSEE could be notified as soon as reasonably possible instead of immediately.

BSEE agrees with the commenter's statement that the operator should focus on a safe response to an active well control incident. The immediate reporting requirement is not intended to undermine safety, and safe operations always take precedence over satisfying reporting requirements. As discussed above in a similar comment to reporting any sea ice movement or condition that has the potential to affect operations or trigger ice management activities, the requirements finalized in this rulemaking allow 24 hours for the written report to be completed. It is appropriate to immediately provide an oral notification to the onsite inspector or Regional Supervisor as soon as an event or potential event is recognized. Accordingly, BSEE disagrees that this provision should be removed or revised. With the BSEE inspector on the rig during Alaska OCS exploratory drilling operations, an immediate oral report to that inspector is not only reasonable, but would not burden the operator. The provision also allows for notification to the Regional Supervisor if no inspector is onsite. Such notification is important to BSEE's fulfillment of its mandate to oversee operations to ensure safety and environmental protection.

One commenter asserted that the kick reporting requirement is more appropriate for inclusion in the Well Control final rule because there is no Arctic-specific reason to report kicks immediately.

BSEE evaluated this comment and determined it is appropriate to implement Arctic OCS specific requirements for kick reporting. As discussed in this preamble, the challenges to conducting operations and responding to emergencies in the extreme and variable environmental and weather conditions in the Arctic are demanding and distinct from those present in other OCS regions. Exploratory operations from MODUs on the Arctic OCS are conducted in sub-freezing temperatures, significant fog cover in the summer, strong winds and currents, storms that produce freezing spray and dangerous sea states, snow, and significant ice cover. Because of these conditions, the challenges of responding to kicks, and any resulting loss of well control, on the Arctic OCS are sufficiently distinct to justify distinct treatment. The Well Control Rule has national application and is therefore not the appropriate regulatory vehicle to address Arctic-specific concerns.

Three commenters request clarification that it is not BSEE's intent to direct well control activities beginning with any unexpected kick. The commenters assert that premature regulator intervention would increase confusion and any existing risks pertaining to the status of the well under such circumstances. Commenters also assert that including kick occurrence information with the daily and weekly well activity reports provides BSEE with the information it needs related to kick occurrence.

BSEE does not intend to direct well control activities and acknowledges that the operator is responsible for any immediate response to ensure the safety of the crew and facility. The notification requirements are within BSEE's authority to monitor and review any actions that may lead to a loss of well control. As described previously, safe operations are the primary concern. This requirement does not state, nor is there an implication, that the regulator will intervene in operations. However, proper response involves providing the regulator with timely and accurate information, so that it is actively aware of threats to well control. Merely including this information in well activity reports does not provide BSEE the information in a suitable timeframe.

One commenter requested that BSEE clarify what kicks are considered "unexpected" and could result in loss of well control. The commenter suggests that BSEE should provide reporting thresholds (*e.g.*, kick size) to assist operators in complying with this provision.

BSEE disagrees. The kick reporting requirement deliberately does not provide for the commenter's suggested reporting threshold. To the first part of the commenter's request, "unexpected" is intended to have its ordinary, typical definition, and an "unexpected" kick is one that is not anticipated in the course of normal operations and that could result in loss of well control. As with the ice management reporting requirements discussed above, BSEE determined not to prescriptively limit the reporting requirement to certain threshold triggers because it is essential for operators to remain in close communication with BSEE about any operational issues that are unexpected and could result in a loss of well control. Just as the operator needs to have sufficient time to act in the event of an incident that poses an operational hazard, BSEE would need sufficient time to oversee the safety of an operator's reactions and prepare to respond if a response is necessary due to a safety or environmental incident.

One commenter asked whether contractors or individuals are required to ascertain if the operator made the required reports, and to report independently if they have not.

As a general matter, BSEE looks to the designated operator to make filings and reports on behalf of all lessees and owners of operating rights. Because existing § 250.146(c) states that when a regulation requires that a lessee take an action, the person actually performing the activity is also responsible for complying with that requirement, it follows that the lessees' reporting duties could extend to a contractor to the extent that contractor actually performs the activity.

Documents Incorporated by Reference (§ 250.198)

The existing regulations at § 250.198 identify what documents BSEE has incorporated by reference. BSEE proposed to add paragraph (h)(95) to existing § 250.198 to incorporate by reference the API RP 2N, *Recommended Practice for Planning, Designing, and Constructing Structures and Pipelines for Arctic Conditions,* Third Edition. This document is a voluntary consensus standard addressing the unique Arctic OCS conditions that affect the planning, design, and construction of systems used in Arctic and sub-Arctic environments. This API document—which is virtually identical to a standard previously issued by the International Organization for Standardization (ISO), "Petroleum and Natural Gas Industries Arctic Offshore Structures," First Edition (2010) (ISO 19906)—would be appropriate for certain aspects of drilling operations, such as accounting for the severe weather and thermal effects on structures, maintenance procedures, and safety. Since this final rule is focused on the exploratory drilling phase of operations on the Arctic OCS, certain portions of API RP 2N, Third edition (such as those related to issues regarding structural and pipeline integrity) would not be relevant. However, many elements of API RP 2N, Third edition could be effectively applied to equipment used in exploratory drilling operations on the Arctic OCS.

Several comments were received on this section. BSEE evaluated these comments and decided to finalize § 250.198 as proposed. Additional comments specific to the requirement to comply with applicable provisions of API RP 2N Third edition, are discussed in responses to comments on paragraph (g) of § 250.470, *What additional information must I submit with my APD for Arctic OCS exploratory drilling operations?*.

Several commenters oppose incorporating API RP 2N Third edition because, at the time of publication of the NPRM, API RP 2N Third edition was in draft form. Therefore, they assert that the final version should not be incorporated in the final rule. One of the commenters requested an additional 30-day public review and comment period for the final API RP 2N Third edition. Additionally, several commenters suggested that ISO 19906 should be incorporated by reference.

BSEE disagrees. Since the effect of incorporating a document by reference is no different than printing the requirement directly in the **Federal Register** (*see* 5 U.S.C. 552(a)(1), the same principles that normally apply to the relationship between proposed and final rules would apply to the relationship between proposals to incorporate a document by reference and the final incorporation by reference of a document. Accordingly, the **Federal Register** contemplated that an agency may propose one standard for incorporation and finalize a rule with a different standard based on changed circumstances or public comments (79 FR 66267, 66268 (November 7, 2014)).

The relevant question is whether the NPRM's discussion of draft API RP 2N Third Edition gave adequate notice of the requirements that the Department is now finalizing. The test for adequate notice is whether the final rule is a logical outgrowth of the proposed rule.[18] Incorporation of the final version of API RP 2N Third Edition is a logical outgrowth of the proposal to incorporate the draft version of the same standard. The final version of API RP 2N Third Edition is largely identical to the version referenced at the time of the proposed rule. The principal change from the draft to the final was the removal of two paragraphs from Section 7.2.2.4 of the final version of API RP 2N Third Edition. This deletion does not meaningfully alter the substance of API RP 2N Third Edition in a manner not logically related to or reasonably foreseeable from the proposed incorporation. The final version allows that that the relevant probability levels associated with abnormal-level ice events are not specifically mandatory as was proposed, but are instead recommended. The effect of this change should be small since, whether the language in the standard is mandatory or hortatory, the regulation—like the proposed rule—requires operators to describe in their APD how they will utilize the best practices of API RP 2N Third Edition. Moreover, the preamble discussed the possibility of finalizing a rule incorporating ISO 19906, which was characterized in the preamble as "virtually identical" to the draft version of API RP 2N Third Edition (80 FR 9916, 9938 (Feb. 24, 2015)). This discussion put the public on notice that the document incorporated in the final rule may not be actually identical to the draft version of API RP 2N Third Edition. The final version of API RP 2N Third Edition incorporated into this rule remains largely identical to the ISO 19906 standard recommended for incorporation by the commenter.

One commenter asserted that BSEE should not incorporate ISO 19906 through the rulemaking because it does not apply specifically to MODUs.

BSEE disagrees. Although we are incorporating by reference the applicable provisions of API RP 2N Third Edition, rather than ISO 19906, the rationale is identical. While the commenter is correct that ISO 19906 (or API RP 2N Third Edition) does not apply specifically to MODUs, the procedures relating to ice actions and ice management contained in the standards can be applied to such units. The rule does not purport to incorporate and apply to MODUs every aspect of these standards, but rather requires the operator to describe how it will utilize the relevant best practices and specifically identifies portions that are not applicable.

Two commenters oppose the incorporation by reference of API RP 2N Third Edition because its incorporation by reference into BSEE regulations conflicts with API's intent that RPs should not be applied inflexibly and should not replace sound engineering judgment. BSEE disagrees that there is a conflict between the finalized incorporation by reference provisions of this rule and the intent of RPs. As stated in finalized § 250.470(g), an operator must comply with the incorporated provisions of API RP 2N Third Edition where it does not conflict with other Arctic OCS requirements under 30 CFR part 250, and must provide a detailed description of how the operator will utilize the best practices included in API RP 2N Third Edition. Accordingly, the flexibility of the application of RP 2N Third Edition is retained while providing for regulatory oversight of how the provisions will be tailored to each APD.

Two commenters suggest lease operators and drilling contractors utilize applicable class rules from classification societies recognized by the International Association of Classification Societies (IACS) to determine what, if any, measures need to be taken from a vessel structure and equipment perspective based upon the area of operations and the seasonal conditions that are expected to be encountered. Another commenter also opposed the incorporation of API RP 2N Third Edition, or ISO equivalents, as an absolute requirement due to the variability of operations that may be conducted in the Arctic and the potential restrictions that could result from such a prescriptive requirement. The commenter recommended the rules focus on operators proving critical equipment fit for Arctic use based on the specific operating environment and assumptions for the given project.

BSEE disagrees. We recognize that MODUs are designed for a specific set of criteria or are classed for a specific environment, water depth, and drilling capacity which, in combination, establishes the design limits of the MODU. Because MODUs are not traditionally designed and/or classed specifically for the environmental conditions found in the Arctic region, it is necessary, if MODUs are to be considered for exploratory drilling on the Arctic OCS, to have in place criteria for the assessment of the site and the MODU for these uniquely challenging operating conditions. API RP 2N Third Edition is the current industry standard that, although not specifically applicable to MODUs, provides the criteria for site and MODU assessment because the procedures relating to ice actions and ice management contained in the standards can be applied to such units. Even if the MODU is reclassified or redesigned for Arctic conditions, operators will still need to perform an assessment for the specific environmental conditions during the planned window of operations of the MODU on the Arctic OCS in compliance with the final APD requirements of § 250.470. Equipment on the MODU used to support the drilling operations should also be evaluated for suitability for Arctic conditions, but should be evaluated using the appropriate standards for equipment operating in the Arctic environment, not a structural design standard for the Arctic region. BSEE's existing regulation at § 250.418(f) requires that operators include in their APD evidence that, in areas subject to subfreezing conditions

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[18] *See Long Island Care at Home, Ltd.*, v. *Coke*, 551 U.S. 158 (2007).

"the drilling equipment, BOP systems and components, diverter systems, and other associated equipment and materials are suitable for operating under such conditions", while final § 250.473(a) establishes a requirement for use of appropriately rated or de-rated equipment and materials. Operators may ensure that proposed materials and equipment are rated or de-rated appropriately by referencing manufacturer specifications and would not need to obtain equipment or material rating by an independent third-party rating entity.

Two commenters recommended other international standards, such as the International Maritime Organization (IMO) Standard for Ships Operating in Polar Waters, 2010 Edition and the Arctic Council Arctic Offshore Oil and Gas Guidelines, should be considered for incorporation by reference.

For this final rule, BSEE has determined that the incorporation by reference of the applicable provisions of API RP 2N Third Edition codifies appropriate standards to regulate MODUs and jack-up rigs conducting exploratory drilling operations on the Arctic OCS. BSEE will continue to review other standards to determine their applicability and the propriety of incorporating them, in addition to API RP 2N Third Edition, to support Arctic OCS exploration using MODUs.

One commenter does not support the incorporation of ISO 19905–1 in the final rule. Another commenter noted BSEE should be aware of the limited applicability of ISO 19905–1 to the assessment of self-elevating units, while ISO 19906 is intended to be used irrespective of structure type. The commenter points out that ISO 19905–1 relies on ISO 19906 for the determination of ice actions which, in practice, means that ISO 19906 has to be used as well.

BSEE agrees with the commenter and determined to incorporate by reference API RP 2N Third Edition. BSEE also agrees with the comment regarding the relationship between ISO 19905–1 and ISO 19906. BSEE recognizes that MODUs are designed for a specific set of criteria or are classed for a specific environment, water depth, and drilling capacity which, in combination, establishes the design limits of the MODU. API RP 2N Third Edition is the current industry standard that provides the criteria for site and MODU assessment. If industry develops additional standards or guidelines for the assessment of MODUs in the Arctic region, then BSEE may consider those during future rulemakings.

Two commenters recommended that any standards incorporated by reference should be available online to the public free of charge. One of the commenters asserted that because the documents were not freely available during the public comment period, neither API RP 2N Third Edition nor ISO 19906 qualify as being "reasonably available" as discussed in the **Federal Register**'s final rule, *Incorporation by Reference* (79 FR 66267, November 7, 2014).

BSEE disagrees with the assertions of these commenters. The **Federal Register** requires that, for a proposed rule, the preamble must: (1) Discuss the ways that the materials it proposes to incorporate by reference are reasonably available to interested parties or how it worked to make those materials reasonably available to interested parties; and (2) Summarize the material it proposes to incorporate by reference. (1 CFR 51.5(a)). The proposed rule preamble met both requirements.

First, it included a discussion of how interested parties could view a copy of the draft version of API RP 2N Third Edition, and it stated that once the standard was finalized by API it would continue to be available on API's Web site for free viewing or for purchase in electronic or hard copy. Specifically, the NPRM preamble stated: "BSEE proposes to incorporate, with certain exclusions discussed later in this proposed rule, draft proposed API RP 2N, Third Edition, which is available for free public viewing during the API balloting process on API's Web site at: *http://mycommittees.api.org/standards/ecs/sc2/default.aspx* (click on the title of the document to open). When finalized by API, that standard will be available for free public viewing on API's Web site at: *http://publications.api.org*", (80 FR 9916, 9933 (Feb. 24, 2015)). (A footnote to this text explained that, to find the document on API's Web site, a user had to first create an account and accept the terms and conditions before it could browse through documents.) The commenters are incorrect to assert that the document was not available for free online either during the comment period for this rulemaking or after finalization of this rule or the API standard. Additionally, as is stated in the preamble of the proposed rule, the documents may be inspected, upon request, at the BSEE office in Sterling, Virginia (45600 Woodland Road, Sterling, VA 20166 (phone: 703–787–1587) or at the National Archives and Records Administration (NARA). For information on the availability of materials at NARA, call 202–741–6030, or go to: *www.archives.gov/federal-register/cfr/ibr-locations.html.*

Further, BSEE is permitted to incorporate by reference (IBR) copyrighted materials into its regulations, and the OFR has expressly concluded that an agency's IBR of copyrighted material does not result in the loss of that copyright.[19] Implicit within that is the fact that access to certain incorporated standards is controlled principally by the third party copyright holder. While BSEE works diligently to maximize the accessibility of incorporated documents, and offers direction to where the materials are reasonably available, it also must ultimately respect the publisher's copyright. Accordingly, most issues related to how API administers access to its copyrighted materials—including its decision to charge for them—are outside of BSEE's control.

The **Federal Register**'s regulations state that, if a proposed rule does not meet the applicable IBR requirements, the Federal Register Director would return the proposed rule to the agency, 1 CFR 1.3. That did not occur here. There is no requirement that such documents be available either online or for free. See 79 FR 66269–72 (Nov. 7, 2014) (discussing the reasons that the **Federal Register** specifically declined to include such requirements in its regulations on IBR).

Second, the preamble to the proposed rule also included a summary of the RP 2N Third Edition. Early on the preamble stated that the document "would be appropriate for certain aspects of drilling operations, such as accounting for the severe weather and thermal effects on structures, maintenance procedures, and safety." (80 FR 9932). Later, describing which parts of RP 2N would not apply, the preamble indicates different kinds of structures that are covered under RP 2N and are subject to BSEE's jurisdiction. *Id.* at 9938 ("For example, Class requirements do not cover the derrick, plumbing, pipes, tubing, and pumps that are all also structural components of a MODU and that fall under BSEE jurisdiction.").

Two commenters recommend the regulations include a complete and clearly organized summary of the API RP 2N Third Edition provisions being incorporated. One of the commenters asserted that the rule should include a technical evaluation explaining the criteria used to determine whether a provision is incorporated by reference, and that before incorporating a document by reference into the regulations, BSEE should be required to show that it has reviewed the document and has determined that it meets the best available and safest technology and operating practices standard.

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[19] *See* 79 FR 66273 (Nov. 7, 2014) ("recent developments in Federal law . . . have not eliminated the availability of copyright protection for privately developed codes and standards referenced in or incorporated into federal regulations"); *see also Veeck* v. *Southern Building Code Congress Int'l, Inc.*, 293 F.3d 791 (5th Cir. 2002).

BSEE disagrees. The preamble to the NPRM included a summary of API RP 2N Third Edition. The NPRM preamble stated that the document "would be appropriate for certain aspects of drilling operations, such as accounting for the severe weather and thermal effects on structures, maintenance procedures, and safety" (80 FR at 9932). It also described which parts of RP 2N Third Edition would not apply, and the preamble indicated which kinds of structures are covered under RP 2N Third Edition and subject to BSEE's jurisdiction. *Id.* at 9938 ("For example, Class requirements do not cover the derrick, plumbing, pipes, tubing, and pumps that are all also structural components of a MODU and that fall under BSEE jurisdiction."). BSEE thoroughly evaluated API RP 2N Third Edition and described in § 250.470(g) the manner in which it was being incorporated into the rules, including which aspects of the RP were expressly excluded from incorporation. BSEE disagrees that the other thresholds suggested by the commenter are necessary or appropriate prerequisites for incorporation of a standard by reference.

Pollution Prevention (§ 250.300)

BSEE proposed to revise § 250.300 pollution prevention regulations to address Arctic OCS exploratory drilling operations by adding provisions in paragraphs (b)(1) and (2). These provisions would require that, during exploratory drilling operations on the Arctic OCS, the operator must capture all petroleum-based mud, and associated cuttings from operations that use petroleum-based mud, to prevent their discharge into the marine environment. The provisions also state that the Regional Supervisor may require capture of all water-based mud, and associated cuttings, from operations after completion of the hole for the conductor casing to prevent its discharge into the marine environment based on certain conditions such as: Proximity of drilling operations to subsistence hunting and fishing locations; the extent to which discharged mud or cuttings may cause marine mammals to alter their migratory patterns in a manner that impedes subsistence users' access to, or use of, those resources, or increases the risk of injury to subsistence users; or the extent to which discharged mud or cuttings may adversely affect marine mammals, fish, or their habitat.

Several comments were received on this section. BSEE has reviewed the comments and determined, with the exception of various technical edits, the substantive provisions of § 250.188 are finalized as proposed.

Many commenters assert that the pollution prevention requirements set forth in the revisions to § 250.300 are unnecessary and redundant with existing authorities or exceed BOEM and BSEE's jurisdiction. Several commenters further assert that the provisions specifically duplicate or conflict with EPA regulations under the CWA, as implemented through National Pollution Discharge Elimination System (NPDES) general permits and strict monitoring requirements. One commenter suggests that BOEM and BSEE should defer to the National Oceanic and Atmospheric Administration (NOAA), National Marine Fisheries Service (NMFS) and its Incidental Harassment Authorization program with respect to potential impacts on marine mammals and subsistence hunting activities.

BSEE disagrees with the commenters. BSEE has the authority to implement the proposed changes to § 250.300, and furthermore the pollution prevention provisions of this final rule do not conflict with the authority of other agencies, such as the EPA and NOAA, to regulate discharges into the marine environment from oil and gas operations on the OCS.

Under OCSLA, BOEM and BSEE are jointly responsible for implementing environmental safeguards to ensure that oil and gas exploration and production activities on the OCS are conducted in a manner which minimizes damage to the environment and dangers to life or health, which provides for the conservation of the natural resources of the OCS, and which will not be unduly harmful to aquatic life in the area, result in pollution, create hazardous or unsafe conditions, or unreasonably interfere with other users of the area.[20] BSEE is fulfilling this obligation by preventing petroleum-based drilling mud and associated cuttings from entering the Arctic environment and by clarifying BSEE's authority to limit the release of water-based mud and associated cuttings in appropriate contexts, such as when operations are near areas where marine mammals may be concentrated or near important subsistence hunting and fishing locations. The changes to § 250.300 are fully within our authority under OCSLA.

E.O. 12777 delegated the functions vested in the President by section 311(j)(1)(C) of the CWA to the Secretary, among others. These delegations establish a cooperative and complementary system for implementing the requirements of the CWA among the Secretary, EPA, NOAA, and others. The functions delegated to the Secretary authorize the Secretary to establish procedures, methods and equipment and other requirements for equipment to prevent and contain discharges of oil and hazardous substances from offshore facilities. The revised language of § 250.300 is consistent with this authorization and does not conflict with any other delegation of authority. By requiring the capture of mud and cuttings associated with exploratory drilling operations on the Arctic OCS under the identified conditions, BSEE is establishing procedures, methods, equipment and requirements for equipment to prevent or contain the discharge of oil and hazardous substances from offshore facilities, as is contemplated by section 311(j)(1)(C) of the CWA. Thus, the changes to § 250.300 are fully within BSEE's authority under the CWA.

The revisions do not conflict with the NPDES general permits issued by the EPA in November 2012. The NPDES permits authorize certain discharges from oil and gas exploratory facilities on the OCS in the Beaufort Sea and the Chukchi Sea, including certain discharges of water-based drilling fluids and drill cuttings, subject to effluent limitations and other requirements. The permits do not allow the discharge of oil-based drilling fluids in any location or at any time or the discharge of water-based drilling fluids and drill cuttings during the fall bowhead whale hunt in the Beaufort Sea. The revisions to § 250.300 are designed to complement, and do not conflict with, these permits. Further, as an agency statutorily responsible for minimizing environmental damage from oil and gas exploration activities on the OCS, BSEE has the authority to issue regulations that are more stringent than the NPDES permits issued by EPA. Nothing about the EPA's authority to regulate pursuant to the CWA detracts from the Secretary's delegated OPA authority under E.O. 12777 or direct authority under OCSLA.

Finally, when writing the rule, BSEE consulted with the EPA, NOAA, and other Federal agencies about regulating discharges from operations on the OCS. In addition, once this rule is final, BSEE will continue its practice of communicating with other agencies responsible for oversight of discharges related to oil and gas exploration drilling in the Arctic. This communication will help ensure that conflicts do not arise.

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[20] *See, e.g.,* 43 U.S.C. 1332(3), 1332(6), 1334(a), 1340(g), 1348(b).

Several commenters were generally supportive of the pollution prevention requirements, but request that the requirements mandate the capture of all water-based mud and cuttings. One of these commenters also asserted the operator should have the burden of demonstrating lack of harm associated with waste discharges, noting subsistence hunting concerns, because marine mammals traverse through areas where the regulated pollution may be discharged.

BOEM and BSEE do not agree that all water-based mud and cuttings must be captured. This final rule implements the statutory mandate under OCSLA to promote oil and gas development while protecting the environment. The Bureaus have not seen sufficient evidence to suggest that water-based mud and associated cuttings are sufficiently problematic in all circumstances to justify a uniform capture requirement. Regarding the comment recommending the operator bear the burden of demonstrating a lack of harm to subsistence hunting, we determined that the final rule addresses the commenter's concern. For example, the requirements in § 250.300(b)(1) and (2) clarify BSEE's authority to prevent discharges based on potential effects to subsistence hunting activities and environmental concerns related to the marine environment. In addition to OCSLA, BOEM must comply with mandates of other Federal laws (*e.g.,* ESA). Further, DOI initiates Government-to-Government Consultations with federally recognized Tribes and Government-to-ANCSA-Corporation Consultation pursuant to Secretarial policy and direction.

Additionally, during the EP review process BOEM conducts environmental review of the EP, which includes addressing subsistence-harvest patterns, socio-cultural systems, and environmental justice. BOEM's environmental review describes the direct, indirect, and cumulative effects on the offshore and onshore environments expected to occur as a result of exploration activities. BOEM's Environmental Assessments (EA) describe the direct, indirect, and cumulative effects on the offshore and onshore environments expected to occur as a result of implementation of EPs. The analytical conclusions must clearly identify whether potential effects are significant, including through relevant information regarding environmental consequences obtained through consultation and review by interested parties. The EA must also identify the agencies and persons consulted with regard to potential effects associated with activities within an EP. Controversial issues and substantive opposing or conflicting views raised by Federal, State, or local agencies, Tribes, or the public regarding the level of environmental impact of the proposal will be addressed. Relevant approvals are also conditioned on compliance with protective restrictions and mitigations put in place by the U.S. Fish and Wildlife Service (USFWS) and NMFS. Through these and other measures, the Bureaus are able to sufficiently analyze and mitigate impacts to marine mammals and subsistence activities, and no revision to this provision is necessary.

One commenter suggests that any determination to allow the discharge of water-based drilling cuttings be made at the permitting stage to allow the operator adequate time for planning and installation of equipment and resources.

BOEM and BSEE agree that pollution prevention requirements should be considered as early as possible. Any determination by the BSEE Regional Supervisor that the operator must capture all water-based mud from operations after completion of the hole for the conductor casing will be made as soon as feasible, on a case-by-case basis, to allow for consideration of newly discovered impacts and impacts that may result from permit modifications. NEPA analysis of proposed exploration activities will help inform BSEE's determination.

Two commenters support the requirements to capture all petroleum-based muds and associated cuttings. One commenter recommended the provisions contain a narrowly defined exception for technical infeasibility, with the burden of proof placed on the operator to demonstrate technical infeasibility in its EP.

We disagree with the commenter's suggestion to allow an exception for technical infeasibility. We believe it is technically feasible, and a common industry practice today, to collect the petroleum based mud and cuttings and back haul them for disposal at an approved onshore disposal site. Existing regulations already provide for departures and use of alternate procedures under appropriate circumstances.

Several commenters recommend the capture requirement be extended to all discharges. One of the commenters further recommended the prohibition of all discharges when technically feasible, with the burden of proof on the operator, and asserted that there would only be an incremental increase in costs offset by cost savings from avoided discharge monitoring, record keeping, reporting, and sampling for heavy metal contamination in marine sediment.

Under existing § 250.300(b)(1), BSEE already has the authority to restrict the rate of drilling fluid discharges or prescribe alternative methods if environmental or operational concerns are raised. Amendments to the section clarify the Regional Supervisor's authority to impose operational measures that complement EPA's discharge limitations by considering potential impacts to specific components of the Arctic environment, such as subsistence activities, marine resources, and coastal areas.

The EPA has the authority to issue NPDES general permits for discharges under CWA section 301(a), 33 U.S.C. 1311(a), which generally prohibits the discharge of pollutants to the waters of the U.S. unless authorized by a NPDES permit. EPA typically issues NPDES general permits, rather than individual permits, for discharges from offshore oil and gas exploration facilities. The EPA uses the results of Ocean Discharge Criteria Evaluations (ODCE) and traditional knowledge when issuing general permits for oil and gas activities. For example, one of the criteria analyzed by EPA for ODCE is the potential impacts of discharges on human health through direct and indirect pathways. As subsistence hunting is directly related to human health, the EPA can require mitigation practices, such as environmental monitoring programs or restrictions on discharges during subsistence hunting seasons. The EPA addressed subsistence hunting concerns in its October 2012 Environmental Justice Analysis for Support of NPDES General Permits for Oil and Gas Exploration facilities in the Beaufort and Chukchi Seas.

We note the requirements finalized at § 250.300(b)(2) require the capture of all cuttings from Arctic OCS operations that utilize petroleum-based mud and, after consideration of various factors, the Regional Supervisor also has discretion to require the capture of cuttings from operations that utilize water-based mud. Additionally, under existing § 550.202, BOEM ensures, among other things, that the operator conforms to sound conservation practices, does not interfere with other uses of the OCS, and does not cause harm to the human, marine, or coastal environment. Both existing regulations and the requirements finalized at

§ 250.300 provide for both mandatory limitations of discharges of petroleum-based substances and regulatory discretion to prohibit drilling discharges that may be harmful to the marine environment. These requirements complement EPA permitting and regulation of discharges related to OCS operations.

One commenter disagrees with providing the Regional Supervisor discretion to prohibit both water- and petroleum-based mud and cuttings based on environmental factors, including migratory patterns and adverse effects to marine mammals, fish or their habitat. The commenter asserted that there is no scientific evidence suggesting whales detect odors from drilling, let alone respond to odors in a way that would substantially alter their migration patterns. Accordingly, the commenter asserted, concomitant changes to subsistence hunting, such as hypothetically needing to travel farther beyond historic whale migration routes and hunting areas, are not expected.

BSEE has existing authority under § 250.300(b)(1) to restrict drilling fluid discharges or prescribe alternative methods if environmental or operational concerns are raised. Amendments to the section clarify and provide guidance regarding the Regional Supervisor's authority to impose operational measures that complement EPA's discharge limitations by considering potential impacts to specific components of the Arctic environment, such as important subsistence activities, marine resources, and coastal areas. In crafting these amendments, the Bureaus considered all available science-based factors and traditional knowledge and determined the environmental effects of discharges into waters surrounding operations should be one of the factors the Regional Supervisor may consider when prohibiting discharges of water-based muds and associated cuttings. BOEM incorporates both science and traditional knowledge in its environmental documents prepared under the NEPA. This NEPA analysis helps ensure that BOEM and BSEE make decisions based on an understanding of environmental consequences with the intent to protect, restore, and enhance the environment of the Arctic OCS while balancing the Nation's need for oil and gas resources.

One commenter recommended rewording the provisions to allow for a science-based assessment to be reviewed by BSEE and stakeholders as part of a transparent process.

As a standard practice, BOEM and BSEE consult with Federal, State, and local governments, as well as federally recognized Alaska Native Tribes and ANCSA Corporations, and provide opportunities to be informed by the scientific community, non-governmental organizations, and concerned citizens to maintain transparency. However, for activity authorized under OCSLA, final decisions will rest either with BOEM under part 550 authorities or with BSEE under part 250 authorities. These decisions are made to protect the best interests of the Nation and in compliance with other Federal law, including, for example, NEPA, ESA, or the Marine Mammal Protection Act (MMPA).

When and how must I secure a well? (formerly § 250.402)

BSEE proposed to add a new paragraph (c) to the former § 250.402. As discussed in Section IV.A, the contents of § 250.402 were subsequently moved to a new § 250.720 by the Well Control Rule. Therefore the new paragraph (c) has been finalized at § 250.720(c) in this rulemaking. This new paragraph requires exploratory drilling operators on the Arctic OCS to ensure that any equipment left on, near, or in a temporarily abandoned well that has penetrated below the surface casing be secured in a way that would protect the well head and prevent or minimize the likelihood of the integrity of the well or plugs being compromised. The primary concern this provision is designed to address is the possibility that ice floes could sever, dislodge, or drag any exploration-related equipment, obstructions or protrusions left on the well or the adjacent seafloor. The language, however, is drafted to encompass damage from any foreseeable source. The provision in paragraph (c)(1), which is designed to be performance-based, would allow operators to devise optimal strategies for identifying and accounting for threats to the integrity of equipment left on the OCS, and would be limited only to exploration wells that have penetrated below the surface casing.

However, for exploration wells located in an area subject to ice scour, based on a shallow hazards survey, final paragraph (c)(2) would require a mudline cellar or equivalent means of minimizing the risk of damage to the well head and well bore. BSEE added "well bore" to the provision to clarify that ice scour presents risks to equipment located both at the well head and in the well bore. BSEE may approve an equivalent means that will meet or exceed the level of safety and environmental protection required if the operator can show that utilizing a mudline cellar would compromise the stability of the rig, impede access to the well head during a well control event, or otherwise create operational risks. The BSEE Regional Supervisor will evaluate, during the APD process, whether a proposed equivalent approach is sufficiently protective.

Several commenters supported a performance-based approach and recommended that the final rule revise proposed § 250.402(c) to permit an operator to select technology that can best address the source control event according to the operator's plan. One of the commenters argued that a prescriptive approach to regulation stifles innovation, introduces uncertainty and promotes a particular type of spill response technology still in development, at the expense of other approaches combining different components that may provide equal or better protection against risk. This commenter asserted that the rulemaking does not provide a basis for determining how equivalency should or could be demonstrated by an operator or how it would be evaluated by the regulators.

BSEE agrees with the importance of allowing for the use of technology that is best suited to an operator's plan and understands that technology may exist or be developed that provides equal or better protection against risk than that prescribed in the regulation. To clarify this, we are revising the language in proposed § 250.402(c)(2). The finalized regulation at § 250.720(c)(2) establishes a performance standard, while also specifying a prescriptive method for achieving the performance standard. Section 250.720(c)(1) provides that an operator must ensure applicable equipment is "positioned in a manner" that will protect the well head and prevent or minimize the likelihood of compromising the downhole integrity of the well or the effectiveness of the well plugs, but does not dictate how those ends are to be achieved. Additionally, in areas of ice scour, § 250.720(c)(2) specifically allows for "an equivalent" to a well mudline cellar as an alternative means to protect the well head and wellbore. BSEE may approve an equivalent means that will meet or exceed the level of safety and environmental protection required if the operator can show that utilizing a mudline cellar would compromise the stability of the rig, impede access to the well head during a well control event, or otherwise create operational risks. The flexibility provided by these performance-based standards is adequate to address the commenter's concerns.

Existing regulations also facilitate the approval of alternate equipment and procedures. Section 250.141—*May I ever use alternate procedures or equipment?* –allows for the District Manager or Regional Supervisor to approve the use of alternate procedures or equipment provided the operator can show the compliance measures will meet or exceed the level of safety and environmental protection required by this provision.

Regarding the commenters' concern that this rulemaking does not provide a basis for determining how equivalency should or could be demonstrated by an operator or how it would be evaluated by the regulators, we note the concern and have added a discussion in Section III.B to clarify how BSEE implements the provisions of § 250.141. Under § 250.141(c), the operator must submit information or give an oral presentation to the Regional Supervisor describing the site-specific application(s), performance characteristics, and safety features of the proposed procedure or equipment.

One commenter suggested that the final regulations should allow for the use of an open system, such as the use of a rotating head, managed pressure drilling, and/or riser gas handler, as this would allow for closer monitoring of flows and wellbore pressures. The commenter asserted that use of these options would protect against the formation of undetected or unconfirmed hydrocarbons arriving at an open surface arrangement with no backpressure and subsequent violent expansion/release of hydrocarbon gas clouds. The commenter recommended that the system used be determined based on water depth and other well/drilling rig parameters.

BSEE generally agrees, with the qualification that use of a system that incorporates a rotating head device, managed pressure drilling (MPD) technology, and/or riser gas handlers, is only appropriate in certain situations. For example, in settings such as the Gulf of Mexico, particularly in deep water where the safe drilling margin is typically very narrow, this technology has been used effectively. Currently, we are aware of four different MPD type systems available for use in the Gulf of Mexico, including use of a rotating control device. These include the following: (1) Constant bottom hole pressure for drilling in narrow or relatively unknown safe mud weight windows; (2) return flow control for early kick-loss detection; (3) mud cap drilling for drilling in severe to total loss zones with sacrificial fluids; and (4) dual gradient drilling for drilling in water depths greater than 5,000 feet. Use of open systems may have applicability in frontier areas such as the Arctic OCS where additional hydrostatic control may be advantageous to ensure a well is drilled safely. The provisions finalized at § 250.720(c) do not preclude an operator from proposing use of such a system in areas of ice scour. BSEE may approve an equivalent means that will meet or exceed the level of safety and environmental protection provided by a mudline cellar if the operator can show that utilizing a mudline cellar would compromise the stability of the rig, impede access to the well head during a well control event, or otherwise create operational risks. Additionally, an open system may be approved as an alternate procedure or equipment under § 250.141 if it is demonstrated to provide an equivalent means of minimizing risk of damage to the well head and wellbore.

One commenter recommended that BSEE provide guidance regarding the use of a slim-hole "closed" system approach during an initial exploration phase. The commenter asserted that a slim-hole approach may be quite possible in the Arctic and would result in far less impact on the environment for exploration drilling where no incident occurred. Additionally, the commenter asserted that the "closed" system allows for far better monitoring of flows in and out of the well.

BSEE agrees with the comment, as the use of a slim hole "closed" system approach to exploratory drilling operations on the Arctic OCS may have benefits in certain situations. As stated above, the provisions of this section do not preclude an operator from proposing use of such a system, if it can be demonstrated to provide an equivalent means of minimizing risk of damage to the well head. The existing regulations at § 250.141 also allow an operator to propose alternative methods of compliance if they can validate that such proposals provide for an equivalent or greater level of safety to personnel and the environment as what is required in the regulations.

One commenter suggested the use of a comprehensive up-to-date barrier diagram for each well, showing the condition and verification of each component of the barrier system. The commenter suggests that this diagram should be available for all involved to see and for inspection by authorities without notice.

BSEE agrees with having a barrier diagram for each well and has determined the concern is addressed in existing regulations. Section 250.413, *What must my description of well drilling design criteria address?*, requires the operator to submit a well diagram/wellbore schematic that includes the various barriers in a well (*e.g.*, casing, liners, cement, downhole seal assemblies, plugs, drilling fluids, etc.) as part of the information submitted in a typical APD. Barrier information (*e.g.*, packers, tubing, completion fluids, subsurface safety valves) is also required as part of a well completion application in the form of a wellbore schematic. If completion is planned and this data is available at the time the operator submits the APD and Supplemental APD Information Sheets (Forms BSEE–0123 and BSEE–0124), the operator may request approval on those forms. BSEE believes these two schematics adequately address well barriers and that no revisions to the rule are necessary.

One commenter recommended there should be improvements, as appropriate, to the barrier system, specifying that these may include improvements to BOP equipment and to the monitoring and verification of casing/tubular connections.

We agree with the importance of improvements to barrier systems used during the drilling of a well. In addition to improvements enacted through this rulemaking, BSEE finalized several additional improvements to barrier systems in the Well Control Rule. BSEE also participates in various standards development work groups and workshops and has assisted with the preparation of Systems Reliability Technical Evaluations.[21] BSEE has also initiated and funded approximately 30 research projects to assist in implementing various improvements to key barrier systems. Studies of interest being conducted through the agency's Technical Assessment Program (TAP) include TAP #737—Risk Assessment for Life Cycle Management and Failure Reporting Systems and TAP #753—Evaluation of the Collection and Application of Risk Data. Other TAP studies on barriers address BOP system reliability, BOP shearing technology, safety management systems and subsurface safety valves.[22] BSEE has also entered into an Interagency Agreement with Argonne National Laboratories to evaluate risk and further study drilling barrier management, including projects on BOP control systems, shear ram certifications, risk-based inspection and regulatory practices, and risk-based decision making. Accordingly, while BSEE agrees with the importance of continuously pursuing improvements to barrier systems, it does not believe that any revisions to this rule for that purpose are necessary or appropriate at this time.

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[21] *E.g.*, QC–FIT Evaluation of Seal Assembly & Cement Failures Report #2014–02, December 2014, QC–FIT Evaluation of Connector and Bolt Failures Report #2014–01, August 2014.

[22] TAP studies are available at *http://www.bsee.gov/Technology-and-Research/Technology-Assessment-Programs/Categories/Production.*

One commenter cautioned that operations should recognize limits of the casing shoe and potential consequences, should the leak off test pressure be exceeded. The commenter recommended the regulations require an estimate of the shoe strength, updated as information becomes available, and an assessment of what pressures will be imposed upon the shoe (as the weakest point in the openhole section of the wellbore) given the well/formation characteristics, uncertainties and potential interacting operations. The commenter highlights the Frade incident (Chevron, Brazil, 2010) as an example of what can happen when these issues are not adequately addressed.

BSEE is aware of the significance of the Frade incident, during which an estimated 4,600 barrels of oil leaked into the ocean during the drilling of an appraisal well in the Frade Offshore Field off the coast of Brazil, and has held various discussions with Brazil's National Agency of Petroleum, Natural Gas and Biofuels since the incident to better understand its causes. The agency believes that existing regulations at § 250.427, which require a pressure integrity test after drilling at least 10 feet but no more than 50 feet of new hole below the casing shoe, are adequate to prevent such an incident happening on the Arctic OCS, even though these provisions do not require an additional pressure integrity test to update a shoe's strength.

One commenter recommended revising the proposed rule to allow for better flow measurement in and out of the well. The commenter also suggested the need for better understanding of what differences could occur between flow in and flow out, specifying that this is needed where there is hydrocarbon within the flow system. The commenter asserted that it is essential to undertake detailed modeling of potential events in order to recognize potential issues and mitigations to be taken, and ensure that crews are properly and effectively trained.

BSEE agrees with the comment on addressing better measurement of flow in and flow out of a well as a way to improve safety. In December 2015, the agency completed a TAP study, #743-Evaluation of Automated Well Safety, studying early kick detection and managed pressure drilling, including use of a Coriolis meter to monitor flow in/flow out of a wellbore. This study identifies automated well safety technologies with the potential to increase safety during OCS drilling, well completion, well work over and production operations, as well as to assess early well kick detection approaches, equipment, techniques, and systems associated with drilling operations on the OCS. These studies will help us to identify and address improvements in flow measurements.

One commenter recommended that, if a marine riser is used, additional instrumentation should be included to identify and provide alarms to address the presence of previously undetected hydrocarbons in the riser prior to these hydrocarbons reaching the surface.

BSEE agrees with the commenter on the importance of detecting hydrocarbons in a drilling riser and notes that our existing regulations—formerly at § 250.446(b) and moved by the Well Control Rule to new § 250.739(c)—require a visual inspection of the riser at least every three days, weather and sea states permitting. BSEE believes that this requirement is adequate to assure the integrity of this system without installing additional riser instrumentation. Using additional riser instrumentation would not be an effective means of detecting hydrocarbons in drilling risers in the Arctic because of the short riser length needed to conduct shallow water drilling operations like those typically conducted on the Arctic OCS. In the event of a kick, short riser lengths will provide a limited amount of time between when a kick is detected in the wellbore and when the kick reaches the surface. Therefore, using additional riser instrumentation would provide negligible benefit.

One commenter suggests that the final rule should be revised to implement systems addressing approaches for ensuring crew safety and access to the seabed wellhead. The commenter cautions that, for deep water operations (>5000 feet (1524 meters)), it is likely that a dynamically positioned MODU will sink away from the seabed location (wellhead) of a well that has blown out. Additionally, the commenter asserted that forcibly pulling a MODU off of a well that is blowing out may result in a far higher rush of hydrocarbons to the rig floor, with very serious implications for the safety of the crew and the subsequent blow-out events.

BSEE disagrees that revisions to the rule are necessary. We consider access to the wellbore, wellhead and associated top hole equipment to be a part of the evaluation required under the revised § 250.720(c). Under this provision, the operator is required to evaluate equipment needs when moving a drilling rig off a well prior to completion or permanent abandonment to ensure that an appropriate response to potential issues will be available. Regarding the commenter's concern related to dynamically positioned MODUs engaged in deep water operations, it is anticipated that none of the relevant Arctic OCS exploratory drilling operations will be in water depths greater than 5000 feet. However, if operational realities change, the regulations finalized here do address the commenter's concern, as the operator must evaluate equipment needs and ensure appropriate responses to issues (*e.g.,* MODUs sinking away from the wellhead) are available.

One commenter expressed concern with running a capping stack in shallow water, particularly installing a capping stack within the "boil" of a blowing out well. The commenter suggests that using a pre-positioned capping stack may be preferable.

The commenter's concern is addressed in this final rule. The ability to install the capping stack under expected conditions, including within the "boil" of a blowing out well, is required to be evaluated by the operator and presented as a part of their APD. BSEE agrees that there may be situations when the capping stack will not be an appropriate response to a well control event, which is why this is only one part of a series of well control measures proposed in the rule, including containment systems and same season relief well capabilities. Additionally, this final rule does not preclude the use of a pre-positioned capping stack as a part of an operator's proposal, and BSEE will evaluate such proposals on a case-by-case basis. To clarify, we revised the definition of Capping Stack to include one that is pre-positioned and may be utilized below a surface BOP when deemed technically and operationally appropriate, such as when using a jack-up rig with surface trees.

One requested BSEE consider relief well mooring patterns in advance, as the layout and installation of mooring systems may be complicated by the existing mooring system or by the inability to run mooring lines across the "boil" of a blowing out well.

BSEE does not agree that advance positioning of pre-set moorings or partially pre-set moorings for a relief well rig would be appropriate. The actual geometry of a well, including its well depth, surface and downhole locations, wellbore trajectory and water depth, is needed to accurately identify where a rig and its moorings should be located to drill a relief well. Much of this information cannot be determined or predicted in advance of a loss of well control. It is preferable to decide on a relief well mooring location(s) and mooring pattern at the time of an actual blowout, when the appropriate surface and downhole locations, geometry, wellbore trajectory and water depth of a relief well/rig can been determined. The rule does, however, require that the operator describe its plans for execution of relief well operations at both the EP and APD stages.

One commenter stressed the importance of well and rig specific training. The commenter noted it is essential to undertake a detailed modeling of potential events so that potential issues can be recognized, mitigations developed, and crews properly and effectively trained.

BSEE agrees with the importance of the role a well-trained crew plays in achieving safe and professional drilling operations. We believe that the training requirements in our existing regulations already provide the basis for developing this type of crew. Section 250.1501, *What is the goal of my training program?*, requires training to ensure that employees and contractors engaged in well control, deep water well control, or production safety operations understand and can properly perform their duties. Section 250.1915, *What training criteria must be in my SEMS program?*, requires implementation of a training program developed in accordance with employee duties and responsibilities for use in the SEMS programs. These regulatory provisions require adequate training of workers specific to their positions at the relevant location and rig.

Two commenters assert the final rule should require the submittal of a well control plan.

Based on the limited information submitted with these comments, BSEE is assuming the commenter would like to see such a plan developed by an operator and submitted to BSEE as part of the approval of a well. Although BSEE agrees with the commenters that submittal of a well control plan would be of value to personnel safety and environmental protection, for such a plan to have meaningful input into actually controlling a well, the specifics of such a plan would need to be developed after a well control event. Therefore, BSEE does not agree that requiring a new plan as part of the approval of a well is appropriate. The actual response on the rig to a well control event is well specific and needs to be developed at the time of the event in order to capture the actual well depth, wellbore geometry, geology, mud weights, casing and/or liner setting depths, and wellbore properties (*e.g.*, pore pressure, fracture gradient, leak off data). Making assumptions for this information ahead of an actual event will not be of value in combatting a loss of well control.

It is important to note that BSEE already requires general well control plan type information in an operator's APD. In addition to discussing how a diverter system or a BOP will be used during an actual kick or loss of well control situation, the APD discusses general well control procedures (*e.g.*, drilling method, wait and weight method, concurrent method of circulating out a kick) that may be implemented during an actual event. If an actual event takes place, the general information included in the APD will be modified in the field to properly address actual wellbore conditions and geometries. Similar information is also already required at the EP stage through, § 550.213(f) example, the blowout scenario required by § 550.213(g), which addresses planning for response to a blowout, including surface intervention and relief well capabilities.

One commenter contends that the revised regulations would be more effective from the standpoint of management of human and environmental risk in the Arctic offshore if they focused on prevention and alternate methods instead of focusing on a relief well plan. The commenter asserted that prevention through prudent well design and operations should be the primary method for control and containment.

BSEE agrees with the commenter that prevention is an important component of control and containment, but disagrees with the comment that it would make response capability unnecessary. We believe the rule properly focuses on both prevention and response techniques, including relief well plans. Proper control of a well in an emergency is achieved through reliance on a wide variety of techniques that may be employed depending upon the circumstances, including use of a relief well according to the provisions of § 250.472, if needed. These include, but are not limited to: Use of proper operational procedures; safe work practices; well maintained and effective equipment, systems, and technologies; a comprehensive inspection/audit program; use of properly trained employees and contractors capable of performing their job duties within the constraints of the actual rig equipment; and implementation of a robust safety management system. All of these techniques, including a well thought out relief well plan, need to work together to ensure proper well control under all circumstances during drilling operations.

One commenter questioned whether a contractor bears a residual responsibility and/or liability for securing the downhole integrity of the well or the effectiveness of the well plugs.

BSEE notes the operator is the ultimately responsible party for all safety, operational, and environmental concerns during a drilling operation. However, any person performing an activity under a lease issued or maintained under OCSLA must comply with regulations applicable to that activity, is obligated to take corrective action, and is subject to civil penalties for a failure to comply. Under the requirements of § 250.107(a)(1) and (2), all operations on a lease must be performed in a safe and workmanlike manner, and work areas must be maintained in a safe condition. Accordingly, contractors can be held responsible for activities related to securing a well where they actually perform those activities.[23]

One commenter suggests that barrier requirements be qualified for the environmental conditions and time period used, for example, deep set versus shallow set plugs.

BSEE agrees that barriers, dual barriers and otherwise, need to be qualified for the environmental conditions and time period used. The barrier requirements included in this rule and in our existing regulations allow for such barriers to function properly at all times in the environmental conditions (*e.g.*, temperature, pressure, geologic and fluids) to which they are exposed during their operational life. Therefore, both the revisions to § 250.720 in the final rule and the existing BSEE regulations[24] are sufficient to ensure that plugs, whether set deep in the well or at a shallow well depth, are qualified for the environmental conditions and time period used.

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[23] For additional guidance on contractor liability, see BSEE's Interim Policy Document (IPD) No. 12–07, *Issuance of an Incident of Non Compliance (INC) to Contractors* (August 15, 2014), available at *http://www.bsee.gov/uploadedFiles/Issuance%20of%20an%20Incident%20of%20Non%20Compliance%20to%20Contractors.pdf*.

[24] *See, e.g.* regulations at 30 CFR 250.400 through 250.490, subpart D, Oil and Gas Drilling regulations; 250.500 through 250.531, subpart E, Oil and Gas Well-Completion regulations; 250.600 through 250.630, subpart F, Oil and Gas Well-Workover; and 250.1700 through 250.1754, subpart Q, Decommissioning Activities.

One commenter recommended revising proposed § 250.402(c)(2) because they claimed it introduces problems for some drilling platform choices, and because there is no basis for the assumption that the absence of a mudline cellar increases potential risk to the wellbore. The commenter argued that the uniform requirement for a mudline cellar poses special problems for a bottom-founded rig. The commenter also asserted the scope of the proposed requirement for mudline cellars will depend greatly on how areas of ice scour are identified, and suggested that ice scour analysis should be defined in the regulation to ensure objective and reasonable application.

Although BSEE disagrees with the commenter's claim that there is no basis for the assumption that the absence of a mudline cellar increases potential risk to the wellbore, we do agree there may be operational difficulties presented by a uniform requirement for a mudline cellar and did not intend this requirement to be overbroad in its application. The proposed language at § 250.402(c)(2) required the operator to use a mudline cellar in areas of ice scour, while allowing for the use of "equivalent means of minimizing the risk of damage to the well head." To clarify this requirement, we are revising the language in proposed § 250.402(c)(2), as set out in the regulatory text of final § 250.720(c)(2). This revision clarifies that an operator may seek approval of an equivalent means to protect the well head and wellbore if it can also show how a mudline cellar would create operational risks. The operator must demonstrate that the equivalent means of minimizing the risk of damage to the well head and wellbore will meet or exceed the level of safety and environmental protection provided by a mudline cellar. Similar flexibility is provided through existing § 250.141.

Regarding the commenter's suggestion that ice scour analysis should be defined in the regulation, we disagree. BSEE has determined not to prescribe a means of analysis of scour data specific to any one technology to allow for the use of new technologies which may be used to determine ice scour (*e.g.*, satellite, or a currently unknown type of technology) in the future.

One commenter asserted there is no reasonable basis for concluding that ice collision damage to a well head would impair integrity of the well down at the level of a hydrocarbon zone. The commenter suggests the focus of the regulations should be protection against the loss of oil containment, best done with attention to barriers and plugging. The commenter acknowledged that although the proposed rule does allow "equivalent means" to a mudline cellar, no guidance is provided on what might be considered equivalent, and no equivalent alternative is readily apparent.

BSEE disagrees with the premise that protecting the well head should not be a focus of the regulations, nor do we agree that a well head compromised by ice collision would not impair the downhole integrity of the well. Having a mudline cellar in place to protect the wellhead provides an additional protection against a loss of well control and possible release of hydrocarbons to the environment. BSEE further notes that, as discussed in the previous comment, we have revised the language in final § 250.720(c)(2) to clarify what an operator should show when requesting to utilize an equivalent that minimizes risk to both the well head and the well bore under this provision. Additionally, alternative compliance measures may be approved under the requirements of § 250.141, as appropriate. As discussed throughout this preamble, we have included discussion on the criteria BSEE will consider to approve such measures in Section III.B.

What additional information must I submit with my APD? (§ 250.418)

BSEE proposed to add a new paragraph to existing § 250.418. Proposed § 250.418(k) requires operators conducting exploratory drilling operations on the Arctic OCS to provide, with their APD, information concerning how they will comply with the SCCE requirements of § 250.470. No comments were received on the proposed language, and the language is adopted without change, however the paragraph is now designated as paragraph (i) to conform to other, unrelated revisions to § 250.418 finalized in the Well Control Rule). See later in this Section for the discussion of comments on § 250.470 for BSEE's response to comments related to the SCCE requirements.

When must I pressure test the BOP system? (Proposed § 250.447)

Existing § 250.737, finalized in the Well Control Rule, requires a 14-day testing frequency for the BOP hydrostatic pressure test. BSEE had proposed to revise existing § 250.447(b) to implement a 7-day testing frequency for the BOP hydrostatic pressure test for Arctic OCS exploratory drilling operations, increasing the frequency from the 14-day interval currently required for all OCS drilling operations (*see* NPRM, 80 FR 9934–5). BSEE received several comments on the appropriate interval for BOP pressure testing. Many commenters supported retaining the 14-day test cycle for various reasons, while others requested that BSEE require a 7-day test cycle for the Arctic assert that more frequent testing has not been proven to decrease reliability of the equipment and would improve safety and protection of the environment.

We do agree with the commenters' support for additional safety and protection on the Arctic OCS and have determined the current regulations improve safety and protection of the environment. As discussed in Section IV.A, *Summary of Key Changes from the NPRM,* BSEE has decided not to adopt the proposed 7-day testing interval and will maintain the same 14-day test cycle on the Arctic OCS as is required elsewhere on the OCS. We note that § 250.737(a)(4) allows for the District Manager to require more frequent testing if conditions (Arctic or otherwise) or the BOP performance warrant. Additionally, § 250.737(d)(9) requires a function test of the annular and ram BOPs every 7 days, between pressure tests, ensuring the BOP rams will function in all operating conditions.

Many commenters highlighted a lack of evidence that reducing the testing interval of the BOP systems from a 14-day test cycle to a 7-day test cycle would result in an increase of safety. These commenters asserted that more frequent pressure testing has not been shown to increase reliability of the equipment and expressed concerns that the more frequent test cycle would cause increased wear-and-tear and fatigue wear of the BOP components, increase the risk that the BOP system will be damaged during testing, increase the likelihood that a well control event could occur during testing, and unnecessarily shorten the drilling season. Several of the commenters also noted that existing BSEE regulations authorize BSEE to require additional testing frequency, if needed.

BSEE agrees. We are not aware of any reliable data that show that more frequent testing enhances the safety of operations. We also have concluded that there is evidence that frequent testing may increase some risks, as well as increase the time needed for operations. BSEE has determined that existing regulations for BOP hydrostatic pressure testing requirements will remain at the 14-day interval and provide for an appropriate level of safety for exploratory operation on the Arctic OCS. Therefore, we have decided not to finalize the 7-day testing frequency requirement for exploratory drilling on the Arctic OCS.

Several commenters also asserted that a 7-day testing interval would directly conflict with BOP testing requirements finalized in the Well Control Rule for all operations on the OCS, and there is no basis for requiring different BOP testing requirements on the Arctic OCS. The commenters emphasized that BOP testing is not an Arctic-specific issue, as BOP performance is equally important regardless of where the operations are conducted. The commenters asserted that subsea temperatures in the Arctic are very similar to those encountered in deep water in the Gulf of Mexico at the seafloor and, similarly, BOPs operating onshore in the winter at negative temperatures are not subject to more frequent testing. Commenters asserted that, if BSEE requires the 7-day testing schedule for the Arctic OCS, then the question could be raised as to whether the 7-day testing schedule should be instituted for all OCS operations on the basis of greater safety. One commenter recommended that the regulations allow for the operator to demonstrate that the BOP equipment, elastomers, and hydraulic control fluid are suitable for the expected Arctic operating environment, including both surface and subsea conditions, with the specifications reviewed and approved by the appropriate regulatory agency.

BSEE generally agrees with the commenters. After considering all the information available, we have determined that the BOP hydrostatic pressure testing requirements will remain at the 14-day interval. We note that while our decision was based on public comments and available studies rather than the desire for uniformity for all OCS operations, the result is that BOP testing requirements will remain consistent for all oil and gas drilling operations on the OCS. BSEE is confident that the unique operating conditions on the Arctic OCS will be addressed, if needed, by the existing § 250.737 allowance for the District Manager to require more frequent testing if conditions or BOP performance warrant.

Several commenters expressed concern that BSEE did not provide adequate technical analysis or justification for proposing the 7-day BOP test cycle for Arctic OCS operations. These commenters emphasized that BSEE proposed changing the testing interval based only on Shell's voluntary reduction of the testing interval in 2012 and on a request from another organization for more frequent BOP testing. Many of the commenters also referred to research supporting less frequent BOP testing. These commenters asked whether BSEE has obtained other studies or additional information that would suggest more frequent BOP pressure testing will result in safer operations. Commenters noted that worldwide, except for the OCS, the standard for BOP pressure testing is 21 days, and that API RP 53 recommends 21 day BOP pressure testing.

BSEE agrees with the commenters on the importance of technical information and study on this issue. After considering all the available information, we have determined to retain the 14-day BOP testing interval. The proposed requirement for more frequent testing was based in part on how Shell conducted operations in 2012. The decision not to require a 7-day BOP testing interval, however, is based on public comments and available studies. We agree with the commenters highlighting conclusions reached by several studies supporting the decision to retain the 14-day BOP testing interval, including the 1999 Foundation for Scientific and Industrial Research at the Norwegian Institute of Technology (SINTEF) study,[25] the follow up SINTEF study[26] released in 2001, and the study by Tetrahedron, Inc.,[27] which was the basis for the change in regulations (*see* 63 FR 29604, June 1, 1998) from a 7-day BOP test frequency to the current 14-day test frequency.

Regarding commenters' support for a 21-day testing interval, we have determined that available data does not support changes from the general 14-day testing interval at this time. BSEE is aware of concerns that the more frequently BOPs are tested, the more likely the equipment might wear out prematurely, and thus fail to operate properly when needed. Additionally, an operator that believes a different interval is warranted by special circumstances may seek approval from the District Manager of an alternative procedure in accordance with § 250.141 or a departure under § 250.142.

What are the real-time monitoring requirements for Arctic OCS exploratory drilling operations? (§ 250.452)

BSEE proposed to add a new performance-based section in Part 250 that would require real-time data gathering on the BOP control system, the fluid handling systems on the rig, and, if a downhole sensing system is installed, the well's downhole conditions during Arctic OCS exploratory drilling operations. In addition, the proposed provision would have required operators to transmit immediately the data during operations to an onshore location, identified to BSEE prior to well operations, where it must be stored and monitored by personnel who would be capable of interpreting the data and have the authority, in consultation with rig personnel, to initiate any necessary action in response to abnormal events or data. Such personnel must also have the capability for continuous and reliable contact with rig personnel, to ensure the ability to communicate information or instructions between the rig and onshore facility in real-time, while operations are underway.

Several comments were received on this section. As discussed in Section IV.A, *Summary of Key Changes from the NPRM,* BSEE is revising the proposed § 250.452 in response to comments received on the requirements. These revisions clarify the operator's responsibilities for complying with the RTM requirements. The revised proposed section requires operators to transmit data, as it is gathered, to a designated on shore location where it must be stored and monitored by qualified personnel who have the capability for continuous contact with rig personnel.

Several commenters recommended removing the RTM requirements from the final rule. One of the commenters suggested that RTM for a BOP Control System should not be considered as useful as RTM for drilling parameters or Measurement While Drilling (MWD) data feeds. Another of the commenters recommended removing the proposed requirement because it is being addressed in the Well Control Rule.

BSEE disagrees. Due to the harsh environment and remote nature of the Arctic, exploratory drilling on the Arctic OCS, absent additional precautions appropriate to the region, constitutes a significantly higher risk activity than conventional drilling operations in other regions, such as the Gulf of Mexico and southern California. Therefore, we have determined it is appropriate to require RTM as an additional safety precaution for the BOP Control System, among others, as the BOP is one of the major safety barriers for preventing a loss of well control event. Additionally, we disagree that the RTM requirements can be removed from this final rule because the requirement is addressed in the Well Control Rule. The requirements finalized at § 250.452 are applicable to all exploratory drilling on the Arctic OCS, whereas the requirements finalized at § 250.724 in the Well Control Rule only apply to drilling operations using a subsea BOP or surface BOP on a floating unit, or high pressure high temperature (HPHT) drilling operations (*see* 81 FR 25888).

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[25] Holand, Per, Reliability of Subsea BOP Systems for Deepwater Application, Phase II DW, SINTEF, Trondheim, Norway, November 7, 1999.

[26] Unrestricted report, Deepwater Kicks and BOP performance, SINTEF, Final Report, July 2001.

[27] Reliability of Blowout Preventers Tested Under Fourteen and Seven Days Time Interval, Final Report, Tetrahedron, Inc, December 1996. Report available at *http://www.bsee.gov/Technology-and-Research/Technology-Assessment-Programs/Projects/Project-253/.*

Two commenters recommended that BSEE wait to finalize the RTM requirements until the completion of the National Academy of Sciences Marine Board Study.

The Marine Board study report was released in May 2016 and is posted on the BSEE Web site.[28] The study report includes a recommendation for BSEE to pursue a performance-based regulatory framework by focusing on a risk-based regime that determines relevant uses of RTM based on assessed levels of risk and complexity. BSEE believes this rule meets the intent of that recommendation. It represents a balance between performance-based requirements and base-level requirements. BSEE will require basic RTM capabilities for exploratory drilling activities in the Arctic based on the applicable considerations of risk and complexity, as discussed above, but will require operators to assess their own particular operational risks and determine the specific parameters to monitor those risks. It is important to note that the Marine Board study is part of an ongoing research effort by BSEE to better understand RTM technologies and their potential use by industry and BSEE. BSEE completed an internal study on RTM in March 2014, which yielded preliminary recommendations on the use of RTM technology during drilling, completion, workover, and production operations and described possible scenarios in which BSEE could use RTM to enhance its regulatory oversight capabilities. BSEE also commissioned an outside study on RTM, which was completed in January 2014.[29] The outside study provided information and recommendations on several topics, including: (1) The current state/usage of RTM technology; (2) cost-benefit of RTM; (3) training for RTM; (4) critical parameters and operations to monitor with RTM; (5) condition monitoring using RTM; (6) regulatory approach (prescriptive vs. performance-based) for RTM; and (7) automation role for RTM. The Marine Board held the public workshop in April 2015 to review these two study reports and a summary of the workshop is posted on the Marine Board's Web site.[30] BSEE has carefully reviewed the comments received on the proposed rule and the other available information, and concludes that it is appropriate at this time to finalize the RTM provisions of this rule because existing information and wide-spread industry use supports the conclusion that RTM requirements enhance safe drilling operations.

One commenter suggested that the role of RTM in managing emergency situations should be assessed to understand the impact of human factors on performance.

BSEE agrees that human factors play an important role in an effective emergency response, and the way that data streams from programs, including RTM, affect the emergency response decision process should be anticipated and described in the operator's SEMS program. This is in line with API RP 75, which is incorporated by reference into the SEMS regulations and which specifically promotes the consideration of human factors in the design of a SEMS, including as an underlying SEMS principle (Section 1.1.2.n.), in the design of new and modified facilities (Section 2.3.5), in the conduct of hazards analysis (Section 3), in the crafting of operating procedures "to minimize the likelihood of procedural error" (Section 5), in the design of Safe Work Practices (Section 6), and in ensuring that critical equipment is easily accessible for critical tasks (Section 7). Ultimately, the operator is responsible for determining how to effectively integrate RTM and human factors into their emergency response and well control planning.

Three commenters expressed concern about the ability to continue operations in the event of a failure or interruption in the data link to shore. One of the commenters further stated that even when no failure or interruption occurs, RTM data will have a small lag time associated with it and will not be "immediately transmitted."

BSEE agrees it should not be necessary to cease operations just because of a temporary loss of the RTM data feed. In this type of situation, the operator should have the ability to gather and record the data in the control room of the offshore unit and transmit the data to shore once the data feed is restored. To clarify this point, we deleted the word "immediately" from the proposed text and revised the first sentence of final § 250.452(b) to state that during well operations, you must transmit the data identified in paragraph (a) as they are gathered, barring unforeseeable or unpreventable interruptions in transmission, and have the capability to monitor the data onshore, using qualified personnel. Onshore personnel who monitor real-time data must have the capability to contact rig personnel during operations. Additionally, to clarify that in the event of a failure or interruption of the datalink the operator should continue collecting RTM data, we added qualifying language to § 250.452(a), providing that the monitoring system must be "independent, automatic, and continuous" to ensure the operator is able to transmit data, even if not immediately, in a timely and appropriate manner. *See* Section IV. A for a complete discussion of changes from the proposed regulatory text of § 250.452.

Three commenters recommended that operators should have the flexibility to develop a performance-based approach to state in their EP or APD which functions will be monitored.

We agree with the comment and have deleted "all aspects of" from § 250.452(a) to allow flexibility for a more performance-based approach. An operator can explain which functions of the identified systems will be monitored in their EP or APD.

One commenter recommended the parameters of RTM should be more defined.

BSEE disagrees. We determined that defining exact parameters in this regulation would be overly prescriptive. BSEE believes guidance documents and industry standards are the best way to define important parameters for RTM as this technology continues to advance.

Several commenters cautioned that the proposed RTM requirements shift operational decision making away from operators and rig personnel and recommended that the language be clarified to affirm that it is the primary responsibility of onboard rig personnel to monitor operations.

BSEE agrees that command and control decision making is typically the primary responsibility of the onboard rig personnel, and the onshore RTM personnel should in most, if not all, scenarios only function in an advisory capacity. It was not BSEE's intent, nor does BSEE agree that the proposed rule text implied, that the RTM requirement would result in a shift of responsibility away from onboard rig personnel. To clarify this point, we deleted the proposed text in § 250.452(b): ". . . and who have the authority, in consultation with rig personnel, to initiate any necessary action in response to abnormal data or events." This revision makes clear that the onboard rig personnel should continue to have the primary responsibility to monitor operations and act accordingly. The RTM monitoring requirements seek to help improve, not disrupt, the ability of onboard rig personnel to monitor operations and assess and mitigate risks. *See* Section IV.A for a complete discussion of changes from the proposed regulatory text of § 250.452.

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[28] Report is available at *http://www.bsee.gov/Technology-and-Research/Technology-Assessment-Programs/Projects/Project-740.*

[29] Summary available at *http://www.bsee.gov/Technology-and-Research/Technology-Assessment-Programs/Projects/Project-707.*

[30] Summary available at *http://www.trb.org/main/blurbs/173606.aspx.*

One commenter asked whether there is an implicit requirement for contractors to maintain duplicate records, or ascertain if the required RTM is being undertaken, and to suspend operations if not.

The operator is responsible for overall compliance with the regulations during operations, and the primary monitoring and record-keeping responsibility belongs to the operator. However, under existing § 250.146, a contractor actually performing operations also has the responsibility to comply with regulations applicable to those operations, as does anyone actually performing operations carried out under an OCS lease. Responsibilities for contractors are further clarified in BSEE's Interim Policy Document (IPD) No. 12–07 (August 15, 2012), "Issuance of Incident of Non Compliance (INC) to Contractors." The IPD clarifies that any person performing an activity on a lease issued under OCSLA is responsible for compliance with regulations applicable to that activity, and can be held accountable for noncompliance. Additionally, under existing § 250.1914, an operator's SEMS program must contain appropriate detail in the bridging documents between the operator and any contractors, including the contractor's roles and responsibilities with regard to RTM. Accordingly, a contractor's responsibility for compliance with the RTM provisions depends upon the contractor's role with respect to carrying out the RTM requirements.

One commenter noted that BSEE will be exposed to proprietary and confidential information when they visit an operator's Real Time Operations Center, and will need to be bound by confidentiality agreements.

BSEE agrees that it must protect proprietary information in accordance with Federal law. As Federal regulators, BSEE personnel routinely work with proprietary and confidential information in the course of carrying out their official duties, so this is not a unique issue to RTM. We will employ the same safeguards, training and accountability measures, and oversight to comply with all Federal laws for protecting proprietary and confidential information obtained pursuant to these provisions. To further clarify, we note that BOEM and BSEE routinely protect proprietary information in accordance with existing §§ 250.197 and 550.197, *Data and information to be made available to the public or for limited inspection,* and requirements of controlling law such as the Trade Secrets Act.

One commenter expressed concern that the USCG has not been involved in the development of the RTM requirements, as they have some jurisdiction over these rigs and this monitoring requirement could impact other rig functions and present possible cyber and security threats.

BSEE acknowledges the commenter's concern but disagrees with the basis of the comment. We have shared the proposed and finalized regulatory requirements for RTM, and all other requirements, in this rulemaking with the USCG as part of the interagency review process required by E.O. 12866. Additionally, we have an existing Memorandum of Agreement (MOA) with the USCG discussing shared regulatory responsibilities on MODUs. MOA OCS–08 *Mobile Offshore Drilling Units (MODUs)* (June 4, 2013)[31] addresses issues related to shared RTM responsibilities between USCG and BSEE such as station keeping and dynamic positioning. Although MOA–OCS–08 does not specifically address RTM, it does address the systems and subsystems being monitored. Regarding the cyber risk, because the RTM requirement relates only to remote monitoring of operational aspects and not remote control, there should be reduced risk of the RTM system becoming a significant cyber vulnerability. However, BSEE and the USCG agree there are many aspects of modern offshore oil and gas operations that pose a cyber risk. This topic is being considered outside the scope of this rulemaking effort.

One commenter questioned whether BSEE will expect RTM to reduce the number of BSEE inspectors physically present offshore 24/7 during drilling activity.

The finalized requirements of § 250.452 do not address how much of an inspection presence BSEE will maintain. The variability of inspection presence on any facility is dictated by internal BSEE policy, which accounts for many factors, including inspection resource availability and the relative risk of the operations. BSEE may take into account the availability of RTM among those considerations.

One commenter cautions that RTM technology will increase the current level of complexity in the BOP and suggests that the interaction with software should be addressed through a formal qualification process. The commenter further asserted that the maintenance and repair of BOPs will need to be done to Original Equipment Manufacturer (OEM) recommendations unless otherwise directed by BSEE, but the proposed regulations do not define how this will be enforced.

BSEE agrees with the commenter that RTM technology will increase the complexity of BOPs, but has determined the commenter's concern has been addressed by the requirements finalized in the Well Control Rule at § 250.732, *What are the BSEE-approved verification organization (BAVO) requirements for BOP systems and system components?.* These requirements apply to all BOPs and include a requirement under § 250.732(d)(8) that the BAVO report to BSEE include "[a] comprehensive assessment of the overall system and verification that all components (including mechanical, hydraulic, electrical, and software) are compatible." Also, § 250.732(d)(3) requires that the BAVO report to BSEE include a description of all inspection, repair and maintenance records reviewed, and verification that all repairs, replacement parts, and maintenance meet regulatory requirements, recognized engineering practices, and OEM specifications.

One commenter suggested that qualifying of BOP components for the actual operating conditions through appropriate testing and qualification plans should be extended beyond the rams and shear tests, and all scenarios should be considered.

BSEE disagrees. While it would be ideal to be able to test all the possible forces a BOP could experience when qualifying BOP components, this is usually not practical in a testing laboratory setting. Accordingly, calculations are typically permitted to supplement the testing results and account for the full range of forces that were not otherwise practical to simulate.

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[31] Available at *http://www.bsee.gov/BSEE-Newsroom/Publications-Library/Interagency-Agreements/.*

What additional information must I submit with my APD for Arctic OCS exploratory drilling operations? (§ 250.470)

BSEE proposed to add a new § 250.470, requiring operators to provide Arctic OCS-specific information with their APDs for exploratory drilling. The proposed informational requirements in the new section would be necessary to inform BSEE's evaluation of APDs for Arctic OCS exploratory drilling operations.

Several comments were received on this section. BSEE has evaluated the comments and determined that, with the exception of various technical edits, the substantive provisions of § 250.470 are finalized as proposed.

One commenter recommended that § 250.470 should include a requirement for operators to submit corrective action plans associated only with rectifying any deficiencies in the drilling unit or equipment that have been previously identified by a BSEE inspector on an Incident of Noncompliance (INC).

BSEE disagrees. The regulatory requirements of § 250.470 provides that drilling units and equipment may operate elsewhere outside of the Arctic drilling season, and the rigs may need repairs or maintenance before beginning operations on the Arctic OCS. Accordingly, the operator will need to demonstrate it is fully prepared to drill on the Arctic OCS prior to each drilling season. BSEE inspections are only one aspect of ensuring safe operations. The operator is responsible for ensuring the safety of their equipment by conducting on-going maintenance and repairs, and the operator must identify needed repair and maintenance for the drilling unit and equipment independent of the issuance of any INCs.

One commenter asserted that the APD provisions require an operator to resubmit a significant amount of information that is already included with the EP and the IOP.

BSEE disagrees. The additional information to be submitted with an APD under § 250.470 is not a requirement to re-submit duplicative information. BSEE expects that when the operator submits the APD, it will by then have a detailed plan that will include information on the same topics touched on in the IOP and EP, but that was not available at the time the IOP or EP was submitted. This may include information such as the identity of equipment and vessels to be used, dates of planned operations, and additional information on how the equipment and vessels would be designed for and be capable of performing in Arctic OCS conditions. To the extent that the operator has already provided necessary information in its approved EP, it may reference that information or recreate it with little burden.

One commenter supported the proposal to require detailed Arctic-specific information in the APD, but cautions that this information will be provided too late in the Department's review and approval process to provide adequate opportunity for the public to review and comment on this information. The commenter recommended BSEE require the inclusion of this important technical data as part of the IOP and EP review, in which outside parties may participate. The commenter recommended, as an alternative if BSEE prefers to require this important information only in the APD application, that the regulations be revised to include an opportunity for "outsiders" to participate in APD review.

BSEE agrees with the commenter's statements on the importance of the APD, but disagrees with requiring the same information as part of the IOP and EP submissions. The IOP, EP, and APD are intended to allow the operator an opportunity to provide increasingly detailed information that is pertinent to each stage of the exploratory drilling operation approval process. Much of the information submitted with the APD is not expected to be available or relevant when submitting the IOP or EP.

While the commenter's suggestion regarding who should be able to participate in the review of the APD is unclear, we assume it is referring to the public. Since much of the information submitted with an APD will likely contain proprietary information, BSEE does not believe it would be appropriate to involve the public directly in the APD review process. However, we note that the regulatory requirements for the IOP, EP, and APD require the operator to make informational copies available to the public with the proprietary information removed. Operators are required to submit an informational copy of their APD, which will be publicly available on the BSEE.gov Web site: (*http://www.data.bsee.gov/homepg/data_center/plans/apdcombined/master.asp*). The APD is a technical document that explains how an operator will safely drill a well. As part of BSEE's review of the APD, BSEE ensures the APD is consistent with the approved EP, and, if not consistent, the operator must revise the APD or the EP, as appropriate. The EP process affords input during the review process from Federal agencies, State and local governments Tribal governments, ANCSA Corporations, as well as the public. The transparency of both the APD process and the related IOP and EP processes (as described earlier in connection with comments on § 550.206) allow for public review and input throughout the process, as appropriate. Therefore, an additional specific public review process at the APD stage is redundant and unnecessary.

One commenter requested, in addition to the information required under § 250.470(c)(8) and (d), that BSEE require operators to submit documentation describing the criteria they would use for triggering site abandonment due to ice, and an organization chart of the operator's own personnel and subcontractors involved in such an operation. The commenter suggested that the criteria should be defined in quantities easy to observe and measure and should be linked to the operational mode of the MODU and its capacity as defined in the Fitness Requirements of former § 250.417(a). (The Well Control Rule removed and reserved former § 250.417 and moved the contents of that section to new § 250.713.) The commenter recognized that the criteria are indicated in EP requirements under § 550.220(c)(2)(iii). However, the commenter asserted the criteria are not clear because terminology related to ice management is inconsistently applied throughout the proposed regulations. The commenter referenced additional details regarding such criteria found in clause 17 of ISO 19906 (incorporated by § 250.470(g) in API RP 2N Third edition), but which the commenter asserted should be clarified in the rules rather than through IBR.

BSEE disagrees, as the provisions finalized at § 250.470 require the operator to present the required criteria for site abandonment due to ice in a measurable quantity and are in accordance with the Fitness Requirements in paragraph (a) of § 250.713, *What must I provide if I plan to use a mobile offshore drilling unit (MODU) for well operations?*. Section 250.470(c)(7) requires that the operator's APD include information on well-specific drilling objectives, timelines, and updated contingency plans for temporary abandonment of a well, which must include specific information on when and how the operator plans to abandon the well and how the Arctic OCS specific requirements of paragraph (c) of final § 250.720, *When and how must I secure a well?*, will be met. These provisions are specific to Arctic OCS exploratory drilling operations and necessarily cover abandonment due to ice. Additionally, § 250.470(d)(2) requires that the operator to include with its APD a detailed description of weather and ice forecasting capabilities for all phases of the drilling operation and plans for managing ice hazards. Similarly, § 250.470(g) requires compliance with API RP 2N Third Edition, which is largely identical to the standard identified by the commenter, including a description in the APD of how the operator will use relevant best practices included therein. The commenter references the EP requirements set forth in § 550.220(c)(2)(iii), which require the operator to include a description of its weather and ice forecasting and management plans, including the operator's procedures and thresholds for activating ice and weather management systems. The EP and APD requirements are similar, but implicated at different stages of the approval process and utilize different, but similar, terminology. The EP is intended to provide the operator the opportunity to present its overall plan for operations, and the APD is the technical document that provides the operator the opportunity to present details regarding how the plan will be implemented.

The commenter does not explain why requiring the submission of an organization chart would help BSEE's oversight efforts. If conditions require site abandonment, BSEE would deal directly with the operator or the operator's representative to address the situation. The operator would be responsible for directing its personnel and contractors, as appropriate.

One commenter recommended that the APD include a requirement for a written well control plan and evidence of a contract with a well control expert. The commenter asserted that, although written well control plans and contracts with well control experts are industry standard, like other important practices, this minimum standard should be codified in regulation so short-cuts are not taken. The commenter recommended that the Arctic emergency well control plan include information regarding the primary rig, SCCE, secondary relief well rig, and additional well barriers. The commenter further recommended that the well control plan should be site-specific and appropriate for Arctic OCS conditions.

BSEE disagrees with the recommendation to require a written well control plan. BSEE does not require a well control plan because it is the responsibility of the operator to determine how best to address these requirements and ensure they have the appropriate equipment available, the contracts in place, and their personnel properly trained. Additionally, the regulations finalized in this rulemaking build on our existing regulations to ensure that operators address the unique Arctic OCS operating environment in a manner that is site-specific and appropriate for Arctic OCS conditions. Specifically, BSEE has existing well control requirements under various provisions of the Well Control Rule, requirements for diverters and BOPs under § 250.416 and other sections of the Well Control Rule, and information requirements for MODUs under § 250.713 of the Well Control Rule. Existing § 250.713 requires operators who plan to use a MODU to drill to "provide information and data to demonstrate the drilling unit's capability to perform at the proposed drilling location." BSEE has training requirements under part 250, subpart O, *Well Control and Production Safety Training*, with additional training requirements under § 250.1915, as part of SEMS requirements. Further, § 550.213(g) requires submission of a blowout scenario as part of any EP that must address issues such as surface intervention and relief well capabilities. Likewise, the finalized provisions at § 550.220(c)(3) and (4) require Arctic OCS operators to describe in their EPs their plans for complying with the SCCE and relief rig requirements. Accordingly, BSEE believes that the combination of this rule and existing regulations adequately addresses the proposed function of a well control plan.

Paragraph (a), Fitness for Service

Paragraph (a) requires operators to submit a detailed description of the environmental, meteorological and oceanic conditions expected at the well site(s); how their equipment, materials, and drilling unit will be prepared for service in those conditions, and how the drilling unit will be in compliance with the requirements of § 250.713. The information requested by this proposed section for drilling units is not in addition to the requirements of § 250.713, but rather is designed to make clear that, to satisfy the fitness requirements of § 250.713, operators would need to provide details regarding Alaska OCS conditions.

One commenter recommended the Fitness for Service description should illustrate how the drilling unit and its major components can perform in the anticipated conditions of the location and season under which it is expected to operate.

BSEE agrees with the comment and notes that the finalized provisions at § 250.470(a)(2) address the commenter's concern. Paragraph (a)(2) of § 250.470 requires the operator to submit a detailed description of how the equipment, materials, and drilling unit will be prepared for service in the environmental, meteorological, and metocean conditions expected at the well site and how the drilling unit will be in compliance with the provisions of existing § 250.713. Existing § 250.713 requires the operator to provide information and data to demonstrate the drilling unit's capability to perform at the proposed drilling location. This information must include the maximum environmental and operational conditions that the unit is designed to withstand.

One commenter requested clarification on the contractor's or equipment supplier's responsibility for compliance with the specifications to be provided under § 250.470(a)(2). The commenter questioned whether it is reasonable to hold a party other than the applicant for the APD responsible when the selection of the equipment and contractor is presumably based on the APD applicant's foreknowledge of the conditions that can be reasonably expected during operations.

BSEE disagrees. Only the party responsible for submitting the APD is responsible for satisfying the requirements of § 250.470(a)(2) related to the contents of its APD. Whether a contractor is responsible for satisfying those requirements depends on the scope of activities performed by the contractor (*i.e.*, are they responsible for the APD submission?). That said, any party actually performing activities on the OCS is responsible for complying with all applicable requirements in conducting those activities, including any conditions or terms of approved plans and permits. Expectations for anyone performing activities on an OCS lease are clearly established in existing regulations at paragraph (a) of § 250.107, *What must I do to protect health, safety, property and the environment?*. Responsibilities for contractors are further clarified in BSEE's IPD No. 12–07 (August 15, 2012), "Issuance of Incident of Non Compliance (INC) to Contractors." The IPD states BSEE's expectations that all operations be performed in a safe and workmanlike manner and that work areas be maintained in a safe condition. It reiterates that the primary focus of enforcement actions continues to be the lessees' and operators'; however contractors performing regulated activities can be held responsible for compliance with the regulations in their performance of those activities. The IPD establishes the factors BSEE will consider in determining whether to issue INCs to contractors. Accordingly, the scope of a contractor's responsibility for regulatory compliance depends upon the scope of activities performed by that contractor.

Paragraph (b), Well-Specific Transition Operations

Paragraph (b) requires operators to submit with the APD a detailed description of all operations necessary in Arctic OCS conditions for well-specific transition operations. BSEE is requiring details about all of the activities necessary to begin and end drilling operations, and to transition between drilling operations and being under way. Finally, BSEE is requiring information regarding any specific repair and maintenance plans for the drilling unit and equipment associated with commencement or completion of drilling operations. All of the required information would facilitate BSEE's understanding of an operator's program and ensure that the operator complies with lease stipulations, EP conditions, and other permitting requirements.

One commenter recommended that BSEE remove paragraph (b) of § 250.470 because the information requested covers aspects of operations which are regulated by the USCG and do not fall under the jurisdiction of BSEE or BOEM. The commenter alternatively requested that, if BSEE does not delete the paragraph, BSEE provide clarification as to what value will be gained from the information provided, as the agency has no authority over the activities on which it seeks information (for example, daily maintenance activities on vessels and rigs, including diesel engine maintenance routines, greasing routines on cranes, and other basic maintenance).

BSEE disagrees with the commenter regarding removing the noted paragraph, but will explain the value to be gained from the required information. First, the examples the commenter cites, such as diesel engine maintenance routines and "towing," are not required under § 250.470(b). Second, the information requested by BSEE under § 250.470(b) relate directly to operations within the Bureau's authority under OCSLA. For example, 43 U.S.C. 1332(6) declares that "operations in the [OCS] should be conducted in a safe manner by well-trained personnel using technology, precautions, and techniques sufficient to prevent or minimize the likelihood of blowouts, loss of well control, fires, spillage, physical obstruction to other users of the waters or subsoil and seabed, or other occurrences which may cause damage to the environment or to property, or endanger life or health." Under 43 U.S.C. 1334(a), the Secretary has the authority to "prescribe and amend such rules and regulations as [s]he determines to be necessary and proper in order to provide for the prevention of waste and conservation of the natural resources of the [OCS]." Section 1348(b)(2) imposes a duty on lessees and operators to "maintain all operations . . . in compliance with regulations intended to protect persons, property, and the environment on the [OCS]." The information requested under § 250.470(b) will help BSEE to fulfill its mandate under OCSLA by ensuring that all operators are prepared to conduct drilling operations in as safe a manner as possible, especially given the challenges and fragility of the Arctic environment.

Paragraph (b) of § 250.470 requires that the information accompanying an operator's APD must include a detailed description of all transition operations necessary in Arctic OCS conditions to begin and end drilling operations and also requires a detailed description of repair and maintenance plans. Although USCG and BSEE share certain aspects of regulatory oversight of operations on MODUs, BSEE is not requesting information under another agency's jurisdictional authority. First, the information described above relates to matters within the scope of operations overseen by BSEE rather than USCG (*i.e.,* beginning and concluding drilling operations). Further, while the planning necessary to assure fulfillment of OCSLA's mandates in connection with the identified operations may implicate some activities, such as the operation of vessels which are regulated by other Federal agencies, it also informs the Department's oversight functions. Such activities can result in damage to operational equipment critical to DOI-regulated drilling activities, which can in turn compromise, reduce, or force modifications to approved operational or safety capabilities and equipment. Similarly, they can give rise to changes to approved operational schedules, which in the Arctic are particularly critical in light of unique considerations arising from the limited open water season, the timing of recession and encroachment of sea ice at drill sites, marine mammal migrations, and subsistence activities, among other considerations. Agency regulations have long recognized the need to obtain, through the planning process, information touching on activities outside of the Department's direct regulatory jurisdiction but which is relevant to the regulation of operations within its jurisdiction.[32] BSEE needs the requested information to ensure safety of the rig, operation-critical equipment, and personnel, during transitions and while engaged in operations. This information will ensure that potential issues with well-related equipment are addressed.

Paragraph (c), Well-Specific Drilling Objectives and Contingency Plans

Paragraph (c) requires operators to submit "[w]ell-specific drilling objectives, timelines, and updated contingency plans for temporary abandonment of the well." Whereas the corresponding provisions of the finalized IOP regulations and current EP regulations at § 550.211 relate more broadly to the objectives and timelines of the overall proposed exploratory drilling activities, this provision would require an operator to provide "well-specific" information at the APD stage.

One commenter requested that BSEE delete § 250.470(c), reasoning that the contingency plans for temporary abandonment are out of place in this section or at the time in the planning process the section addresses. The commenter asserted that the information requested is highly sensitive and has little nexus to any of BSEE's regulatory authority.

BSEE disagrees. Temporary abandonment is a well operation and is under BSEE authority.[33] Accordingly, BSEE currently has regulations regarding temporary abandonment at §§ 250.1721 through 250.1723. These regulations establish the nationally applicable requirements for how to temporarily abandon a well. The finalized requirements under § 250.470(c) address Arctic-specific considerations related to temporary abandonment, including, among other issues, well-specific contingency plans for temporary abandonment due to ice encroachment. The information supplied under this section will require operators to engage in safety-critical advanced planning regarding when and how the operator would temporarily abandon the well, and will provide BSEE with advance notice of and an opportunity to review those plans. The operator must specifically address how the rig would be moved off location; how the well would be secured; and how the operator will meet the finalized requirements in § 250.720(c) to ensure that equipment left on, near, or in a wellbore is protected. This provision requires information that is critical for BSEE to have to fully evaluate the APD in accordance with its mandates of safety and environmental protection under OCSLA in the challenging Arctic environment. The APD includes the specific details of how the operator will conduct the operations proposed in the EP including, if applicable, contingency plans for temporary well abandonment. The APD is submitted at a point in the planning and approval process at which the operator will have more complete and detailed information specific to the well locations and operations being proposed. With regard to the sensitivity of the data, BSEE will handle any proprietary or confidential information obtained pursuant to this provision in compliance with applicable law, including § 250.197 and the Trade Secrets Act.

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[32] *See, e.g.,* 30 CFR 550.224 (requiring description in EP of the support vessels, offshore vehicles, and aircrafts you will use to support your exploration activities, including maps of travel routes and methods for transportation of fluids, chemicals, and wastes); 550.257 (same for Development and Production Plans (DPPs) and Development Operations Coordination Documents (DOCDs)); 550.225 (requiring description in EP of onshore support facilities to be used to provide supply and service support for the proposed exploration activities); 550.258 (same for DPPs and DOCDs).

[33] *See, e.g.,* 43 U.S.C. 1332(6), 1334(a), 1340(g), 1348(b)(2).

Paragraph (d), Weather and Ice Forecasting and Management

The performance-based provision at paragraph (d) requires an operator to submit: A detailed description of its weather and ice forecasting capability for all phases of the drilling operation, including: "How [it] will ensure the continuous awareness of potential weather and ice hazards at, and during transition between, wells;" its "plans for managing ice hazards and responding to weather events;" and verification that it has the capabilities described in its EP. Operators can verify that they have the capabilities described in their EP by providing appropriate supporting documents (*e.g.*, contracts) for the forecasting and ice management capabilities.

One commenter requested that BSEE strike § 250.470(d), as the information sought in this paragraph is already contained in an operator's Critical Operations and Curtailment Plan (COCP) and Ice Management Plan and should not be duplicated as part of the APD process. The commenter asserted that weather and ice forecasting and monitoring are not well site specific and are not well suited as APD requirements.

BSEE disagrees. It is not BSEE's intent to have the operator submit information that it has already submitted to BOEM or BSEE under other requirements. Rather, the purpose of requiring an operator to submit information on ice and weather forecasting with the APD is to allow an opportunity, if needed, to update and supplement any information already submitted with additional details and information that was not available when the information was submitted previously. BSEE notes the information requested with an APD is not duplicative, and in addition to updating information, the operator is also required to address several new considerations, including how they will ensure continuous awareness of weather and ice hazards at, and during transition between, wells. To the extent that the requested information has been submitted previously, such submissions can be relied upon by reference.

Paragraph (e), Relief Rig Plan

Paragraph (e) requires operators to provide, with their APD, information concerning how they will comply with the relief rig requirements of § 250.472. No comments were received on this provision, and it is finalized as proposed. See below in this Section for the discussion of comments on § 250.472 for BSEE's response to comments related to relief rig requirements.

Paragraph (f), SCCE Capabilities

Paragraph (f) requires operators provide with their APD a statement that the operator has a contract with a provider for SCCE, which is capable of controlling and/or containing a WCD as described in the operator's BOEM approved EP, when proposing to use a MODU to conduct exploratory drilling operations on the Arctic OCS. The information requirements of paragraph (f) include:

1. A detailed description of the operator's or its contractor's SCCE capabilities. The description must include operating assumptions and limitations and information demonstrating that the operator would have access to and the ability to deploy such equipment necessary to stop or capture the flow of an out of control well. This description would allow BSEE to verify the location and availability of this equipment for compliance with § 250.471. This section also requires a detailed description of the operator's ability to evaluate the performance of the well design to determine how it can achieve full shut-in without having reservoir fluids discharged in the environment.

2. An inventory of the equipment, supplies, and services the operator owns or has a contract for locally and regionally, including the identification of each supplier. This information is important because BSEE would need to verify the existence, condition, and location of the equipment that the operator describes in its plans.

3. Where SCCE capabilities are obtained through contracting, proof of contracts or membership agreements with cooperatives, service providers, or other contractors, including information demonstrating the availability of the personnel and/or equipment on a 24-hour per day basis during operations below the surface casing.

4. A description of the procedures for inspecting, testing, and maintaining SCCE. SCCE is intended to be standby equipment. This provision allows BSEE to verify that the operator, or contractor, has procedures in place for inspecting, testing, and maintaining the equipment so that it would be ready for use, if necessary. Operators are already required under existing regulations at § 250.1916 to retain the information requested by this new paragraph. The new provision requires that operators who propose to conduct exploratory drilling on the Arctic OCS submit this information in conjunction with their APD.

5. A description of the operator's plan to demonstrate that personnel are trained to deploy and operate the equipment and that these personnel would maintain ongoing proficiency in source control operations. Standby crews who are not used regularly to perform their dedicated functions would not develop the necessary skills unless they are properly trained, and would not maintain those skills unless that training is reinforced by practice. It is therefore imperative that the operator demonstrate that these personnel have a plan for acquiring, and the ability to maintain, the proficiency necessary to respond when called upon. This requirement would allow BSEE to review those plans and verify that the proficiencies have been acquired and would be maintained.

One commenter suggests that the final rule require operators to submit a detailed plan demonstrating their ability to fully respond to a blowout within three days.

BSEE notes the final rule does require all operators conducting exploratory drilling operations on the Arctic OCS to have in place response plans demonstrating their ability to fully respond to a blowout, beginning within 24 hours after loss of well control. Specifically, revised § 250.471(a) requires that a capping stack be available and positioned to arrive at the well within 24 hours after a loss of well control, and a cap and flow system and a containment dome be positioned to ensure they will arrive at the well location within 7 days after a loss of well control. Revised § 250.472 requires that any time the operator is drilling below or working below the surface casing it must have access to a relief rig, positioned so that it can arrive on site, drill a relief well, kill and abandon the original well, and abandon the relief well prior to expected seasonal ice encroachment at the drill site, but no later than 45 days after the loss of well control. Paragraphs (c)(3) and (4) of § 550.220 require operators to describe in their EP how they will comply with these requirements, and § 250.470(e) and (f) impose similar requirements for APDs. When added to existing regulations (*e.g.,* § 550.213(g)), BSEE has determined that these provisions will provide a reasonable level of environmental protection. BSEE does not agree that a uniform prescriptive three-day response plan is necessary or appropriate. There are many specific requirements in the final rule that will ensure that operators have access to equipment to quickly respond to losses of well control. Such responses will likely depend upon the specific facts and circumstances related to the loss of well control incident at hand and will not benefit from the suggested uniform requirement for a three-day response plan.

One commenter suggests changing the phrasing in § 250.470(f)(2) from "local and regional" in regards to the availability of SCCE, supplies, and services, to "in-region" and "out-of-region" to match common usage in Alaska (see 18 AAC 75.495) and to match oil spill response industry standard terminology.

BSEE disagrees. The provision at § 250.470(f)(2) ensures that the operator has the access to required SCCE within the timeframes established in § 250.471. The terms "local and regional" are used to reinforce that the equipment needs to be in proximate location to meet those standards. BSEE declines to adopt terms of art that may be perceived to have different meanings or connotations.

One commenter requested that BSEE remove § 250.470(f). The commenter asserted that operators should not have to provide this information in the context of each individual APD, as the information requested in paragraph (f) is largely duplicative of information provided elsewhere during the regulatory process. The commenter specifically points to information requested for the EP and IOP.

BSEE disagrees. As discussed above, the requirements of this section, or any provision of § 250.470, are not intended to require operators to resubmit information already submitted to BOEM or BSEE. Rather, the operator is expected to update and supplement the information already submitted and provide more specific or detailed information that was not available when it submitted information for the IOP and EP. To the extent that the operator intends to rely on information already submitted in previously approved submissions, it can do so by reference.

Paragraph (g), API RP 2N, Third Edition

Paragraph (g) requires that operators explain how they utilized API RP 2N, Third Edition, in planning their Arctic OCS exploratory drilling operations. Since the requirements of this final rule are limited only to exploratory drilling operations, operators would not be expected to provide an explanation of how they utilized the entire API RP 2N, Third Edition. This performance-based requirement is limited to those portions of that document that are specifically relevant for exploratory drilling operations. BSEE excludes the following sections of API RP 2N, Third Edition, from incorporation:

1. Sections 6.6.3 through 6.6.4;
2. The foundation recommendations in Section 8.4;
3. Section 9.6;
4. The recommendations for permanently moored systems in Section 9.7;
5. The recommendations for pile foundations in Section 9.10;
6. Section 12;
7. Section 13.2.1;
8. Sections 13.8.1.1, 13.8.2.1, 13.8.2.2, 13.8.2.4 through 13.8.2.7;
9. Sections 13.9.1, 13.9.2, 13.9.4 through 13.9.8;
10. Sections 14 through 16; and
11. Section 18.

One commenter supported the incorporation of API RP 2N Third Edition, but disagreed with the exclusion of three sections. The commenter first opposed the exclusion of API RP 2N clauses 6.6.3 (Ice Gouge) and 6.6.4 (Strudel Scours). The commenter suggests BSEE should consider the possibility of not being able to permanently plug the well before the next open water season, and that by having ice gouge statistics it would also be possible to calculate the actual impact risk to a well head. The commenter also questioned excluding section 13.2.1 (Design Philosophy) and recommended BSEE include a statement that when there is overlap between the requirements in API RP 2N Third Edition and BSEE and/or USCG regulations, the regulatory requirements have precedence.

BSEE carefully considered which sections of API RP 2N Third Edition to incorporate in this rulemaking and determined that certain portions of API RP 2N are not relevant to the exploration stage. Regarding the commenter's first concern with exempting API RP 2N sections 6.6.3 and 6.6.4, the regulations finalized at § 250.470(c) directly address protecting equipment left on, near, or in a wellbore, including protecting the well head and preventing or mitigating threats to the down-hole integrity of the well and well plugs. These regulations are tailored specifically to exploratory drilling operations on the Arctic OCS from MODUs and jack-up rigs, and BSEE determined that sections 6.6.3 and 6.6.4 were therefore not appropriate for incorporation. The commenter's second concern is addressed in § 250.470(g), which requires an operator to comply with the incorporated requirements of API RP 2N "Where it does not conflict with other requirements of this subpart".

One commenter also recommended including API RP 2N Third Edition sections 6.6.3 and 6.6.4, as there is evidence of ice gouging in several locations within the Arctic OCS, which would impact a multi-year drilling program. The commenter asserted that ice gouging should be considered for subsea structures likely to be left over winter, and that strudel scours are widespread along coastal river mouths and should be surveyed as part of planning for an exploratory drilling program in state waters. The commenter also recommended that sections 13.9.6 (Inspection and Maintenance), 13.9.7 (Planning and Operations), and 13.9.8 (Ice Management Plan) be included in the final rule, as they appear to provide a better basis for safe operation than the proposed regulations. The commenter also asked BSEE to consider retaining section 15 (Topsides), as there are a number of issues surrounding winterization of topside structures not under the authority of the USCG, such as wind breaks and insulation of manned work spaces and walkways, and winterization of drilling hydraulics and meters.

BSEE disagrees. Sections 6.6.3 and 6.6.4 were excluded because they address different types of conditions for ice gouging and/or scouring than are anticipated to occur during the Arctic OCS open water drilling season. To the extent the commenter is concerned about facilities remaining on the seabed in connection with multi-year drilling programs, §§ 250.720(c) and 250.470(c) directly address these issues. BSEE also notes that under its OCSLA authority, it does not have jurisdiction over well control operations on State submerged lands. BSEE has authority under the CWA over oil spill response plans related to operations seaward of the coastline, including on state submerged lands. 33 U.S.C. 1321(j)(5); E.O. 12777; 30 CFR part 254, subpart D. In addition, existing BSEE regulations address drilling in frontier areas and include specific requirements related to Arctic OCS conditions, such as ice-scour areas and subfreezing conditions. Specifically, existing § 250.451(h) requires that subsea BOP systems used in an ice-scour area must be installed in a well cellar that is deep enough to ensure that the top of the stack is below the deepest probable ice-scour depth.

Regarding the commenter's recommendation to include sections 13.9.6 through 13.9.8, and section 15, existing § 250.417(c) addresses drilling operations in frontier areas and includes provisions for a contingency plan to include design and operating limitations of the drilling unit where the operator must identify the actions necessary to maintain safety and prevent damage to the environment. Additionally, under existing § 250.418(f), for drilling operations in areas subject to subfreezing conditions, operators are required to include in their APD evidence that the drilling equipment, BOP systems and components, diverter systems, and other associated equipment and materials are suitable for operating under such conditions. Accordingly, BSEE believes that the combination of this rule and existing regulations adequately addresses the commenter's concerns.

One commenter generally agreed with the use of API RP 2N Third Edition, but proposed BSEE also require the operator to document its overall winterization philosophy, as well as specific winterization requirements for MODU drilling systems and equipment.

BSEE disagrees with the commenter's proposal, as the concerns are already addressed in existing rules and with this rulemaking. Although it is not entirely clear what the commenter means by "overall winterization philosophy", existing SEMS requirements at §§ 250.1901 through 250.1933 require the operator to have a SEMS program in place that identifies, addresses and manages safety, environmental hazards and impacts during all phases of drilling operations. Additionally, the finalized revisions to § 250.1920 require an annual SEMS audit for exploratory drilling operations on the Arctic OCS. Regarding specific winterization requirements for MODU drilling system and equipment, BSEE has determined the finalized provisions at § 250.473, which requires operators to ensure that equipment and materials are rated or de-rated for service under conditions that can reasonably be expected during operations, and also utilize measures to address human factors associated with weather conditions that can be reasonably expected while operating on the Arctic OCS, ensure that these issues are adequately addressed.

One commenter suggests that the requirements to comply with API RP 2N Third Edition be replaced with a requirement to meet relevant and applicable class rules from a classification society accepted by the IACS. The commenter also suggests that BSEE replace the requirement for the MODU to meet Ice Class 3 standards with a requirement that the MODU be suitably classed to perform expected activities in the area of operations and the seasonal conditions that are expected to be encountered.

BSEE disagrees. API RP 2N Third Edition specifically addresses oil and gas activities in the Arctic and, although IACS has relevant and applicable class rules, we have determined the incorporation by reference of applicable provisions of RP 2N Third Edition is appropriate. BSEE recognizes that, when applied to MODUs, many of the structural criteria of API RP 2N Third Edition are regulated by the USCG and may be covered by Class requirements for marine structures. Classification is a determination made by private organizations that a vessel has been constructed and maintained in compliance with industry standards to be fit for a particular service.

Regarding the commenter's concern that the MODU be required to meet Ice Class 3 standards, we note that although the preamble to the NPRM did mention Ice Class 3 (*see* 80 FR at 9938) we did not propose a regulatory requirement for MODUs to meet specific ice class requirements. BSEE recognizes that MODUs are designed for a specific set of criteria or are classed for a specific environment, water depth, and drilling capacity which, in combination, establishes the design limits of the MODU. MODUs have not traditionally been designed and/or classed specifically for the environmental conditions found in the Arctic region. It is therefore necessary, if MODUs are to be considered for exploratory drilling on the Arctic OCS, to have in place criteria for the assessment of the site and the MODU for the uniquely challenging operating conditions. API RP 2N Third Edition is the current industry standard that provides the criteria for site and MODU assessment. Even if the MODU is reclassified or redesigned for Arctic conditions, operators will still need to perform an assessment for the specific anticipated environmental conditions during the planned window of operations of the MODU on the Arctic OCS, in compliance with the finalized APD requirements of § 250.470. Equipment on the MODU used to support the drilling operations should also be evaluated for suitability for Arctic conditions, but should be evaluated using the appropriate standards for equipment operating in the Arctic environment, not a structural design standard for the Arctic region. BSEE has determined that its selected approach is preferable to both of the alternatives proposed by the commenter.

One commenter stated that BSEE should honor Clause 1 of API RP 2N Third Edition, which provides that this RP does not apply to MODUs. The commenter cautions that the current approach of § 250.470(g), even with exemptions, requires use of API RP 2N Third Edition in situations for which it was not intended.

BSEE disagrees with the commenter's interpretation of the applicability of API RP 2N Third Edition. While the commenter is correct that API RP 2N Third Edition does not apply specifically to MODUs, the procedures relating to ice actions and ice management contained in the standards are applicable to the assessment of such units. Additionally, API RP 2N Third Edition does not specifically preclude the application of appropriate provisions of the document to MODUs. Accordingly, § 250.470(g) calls upon the operator to provide a description of how it will utilize the best practices set forth in API RP 2N. Within that structure, operators have the inherent ability to address the inapplicability of any particular provisions to their operations.

What are the requirements for Arctic OCS source control and containment? (§ 250.471)

The finalized requirements at § 250.471 are designed to ensure that each operator using a MODU and conducting exploratory drilling on the Arctic OCS will have access to, and can promptly and effectively deploy and operate, surface and subsea control and containment equipment in the event of a loss of well control. In particular, BSEE is requiring that each operator have the ability, in the event of a loss of well control, to cap the well and to capture, contain, and process or properly dispose of any fluids escaping from the well. All SCCE must be mobilized (*i.e.,* begin transit) to the well immediately upon a loss of well control. The rule specifically provides that the SCCE is only necessary when drilling below or working below the surface casing.

Several comments were received on this section. As discussed in Section IV.A, *Summary of Key Changes from the NPRM,* BSEE is revising § 250.471(a) to clearly state that the operator must have access to SCCE equipment capable of "stopping or capturing the flow of an out-of-control well". We are also adding paragraph (i) of § 250.471 to clarify when an operator is requesting approval of alternate compliance measures to the SCCE requirements under the provisions of § 250.141, the operator will need to demonstrate that the proposed alternate compliance measure provides a level of safety and environmental protection that meets or exceeds that required by BSEE regulations, including demonstrating that the alternate compliance measure will be capable of stopping or capturing the flow of an out-of-control well. These revisions are in response to commenters' concerns that the language as originally proposed did not clearly state a performance standard. All other provisions of § 250.471 are finalized as proposed.

Several commenters generally support the provisions. One commenter strongly supported the finalized requirements of § 250.471, but noted for the deployment of technologies such as a capping stack, cap and flow system and a containment dome, there are significant "response gaps": Periods in which a particular response tactic could be expected to be ineffective or impossible to deploy based on historic environmental conditions. In a study funded by BSEE, it was found that dispersants, in-situ burning, and mechanical recovery were viable options on the Arctic OCS only 82 percent, 66 percent, and 57 percent of the time, respectively, even during the summer months. During the winter months, the only viable option would be in-situ burning. The commenter argued that, since oil spill response methods are either only sporadically available or not proven to be reliable in Arctic conditions, emphasizing and requiring source control and containment is absolutely critical.

BSEE agrees that effective source control and subsea containment equipment is a critical response capability on the Arctic OCS. Oil spill response countermeasures used to mitigate spills on the surface of the water are always subject to limitations that may arise due to adverse weather and poor on-scene operating conditions. These concerns are heightened under Arctic OCS conditions. The best way to minimize the effects of spilled oil is to prevent it from entering the water in the first place, which is why BSEE agrees that prompt access to SCCE is a critical part in reducing the impacts of a spill and is requiring such equipment and capabilities in § 250.471.

Several commenters recommend that the detailed requirements for source control and containment be removed from the regulations and replaced with performance-based requirements. One of the commenters cautions that requiring specific types of equipment to respond to a loss of well control incident is ineffective and inefficient since it is based upon the false assumption that a loss of well control incident in the shallow waters of the Beaufort and Chukchi Seas would be the same as a deep water well blowout in the Gulf of Mexico. Another of the commenters specifically suggests that the regulations should allow for a specific type of response to a loss of well control — the diversion of wellbore fluids to a flare buoy surrounded by containment boom located a safe distance from other vessels.

BSEE recognizes that operators need to have some flexibility to select the technology that is best suited to planned operations and that alternative technologies may be developed that offer equal or more protection to personnel and the environment than existing technology. We believe the technologies identified in this provision represent the optimal approach to well control capabilities available for the Arctic OCS. However, BSEE acknowledges that it cannot always predict technological developments made by industry. Therefore, we have revised the proposed language at § 250.471(a) to clarify the performance standard required by this provision: That the operator must have access to SCCE that is capable of stopping or capturing the flow of an out-of-control well. Additionally, as discussed in Sections III.D and IV.A, we have added a paragraph (i) of § 250.471 to clearly state that, when an operator is requesting approval of alternate procedures or equipment to the SCCE requirements under the provisions of § 250.141, the operator must demonstrate that the proposed alternate procedures or equipment provides a level of safety and environmental protection that meets or exceeds that required by BSEE regulations, including demonstrating that the alternate procedures or equipment will be capable of stopping or capturing the flow of an out-of-control well.

In addition, with respect to the ability of operators to utilize alternative technology or procedures, BSEE notes these regulations are intended to ensure that operators have a coordinated and redundant system to provide for adequate safety in exploratory drilling operations on the Arctic OCS. Section 250.471 as finalized contemplates a sequential process based on operator proposals for dealing with Arctic challenges in a risked based manner. In the event of a well control event and failure of the BOP, the first option is to deploy a capping stack. The capping stack is the most immediately deployable equipment of the SCCE options. If the capping stack is not successful, the cap and flow system is the next option. If these options are not deployable, or fail to stop the flow, the containment dome system must be deployed to control the flow during the time it takes the well to bridge off or the relief well to be drilled. Each of these options has a high probability of success, but none is guaranteed to be deployable or successful in all situations. BSEE determined that the finalized provisions provide for the necessary redundancy and sequencing of the responses, based on the time necessary to deploy, and therefore provide sufficient safety and environmental protection to allow for exploratory drilling on the Arctic OCS.

One commenter asserted that the OPA already confers oil spill preparedness and response authority to the operator, USCG and EPA, as well as BSEE through the subject Act and E.O. The commenter cautions that introducing an additional and redundant layer of regulation by BSEE has the potential to lead to confusion and administrative conflicts.

We disagree. BSEE has authority to implement the SCCE requirements under OCSLA. BSEE further disagrees that the finalized requirements of § 250.471 add a redundant layer of regulation that will lead to administrative conflicts. The regulation's focus on equipment related to well control and containment (*i.e.,* preventing release of oil into the environment) complements, rather than conflicts with, the focus on spill response (*i.e.,* cleaning up oil that has been released into the environment) and planning under BSEE's OPA regulations, creating a comprehensive and holistic approach to the relevant issues.

Under OCSLA, BSEE is responsible for implementing environmental safeguards to ensure that oil and gas exploration and production activities on the OCS are conducted in a manner which minimizes damage to the environment and dangers to life or health, provides for the conservation of the natural resources of the OCS, and will not be unduly harmful to aquatic life in the area, result in pollution, create hazardous or unsafe conditions, or unreasonably interfere with other uses of the area.[34] These regulations allow BSEE to fulfill this obligation by requiring equipment that is fundamental to safe and responsible operations on the Arctic OCS. In that environment, existing infrastructure is sparse, the geography and logistics of bringing equipment and resources into the region is challenging, and the time available to mount response operations is limited by changing weather and ice conditions, particularly at the end of the drilling season. BSEE's OCSLA regulations in Part 250 have long addressed issues surrounding source control equipment and capabilities (see, *e.g.*, §§ 250.401, 250.440 through 250.451, 250.515 through 250.517). BSEE has determined that the SCCE requirements of § 250.471 are necessary and appropriate to account for Arctic OCS conditions and fall squarely within its authority under OCSLA.

These SCCE regulations are needed because exploratory drilling operations on the Arctic OCS are distinct from operations on any other part of the OCS. The logistics and transit times necessary to bring critical equipment to bear in the event of a loss of well control, require the operator to plan for and be prepared for contingencies that would be more straightforward to address in other areas of the OCS. Moreover, there is a limited ability in the Arctic region to summon additional source control and containment resources. Accordingly, operators working there must plan for complexities not confronted elsewhere. At some level, redundancy of equipment response options is both appropriate and necessary in this context, where the redundancies that exist as a matter of course in an environment like the Gulf of Mexico are not present. Rather than adding a redundant layer of regulation, these requirements are specifically geared towards the necessities of operating in this uniquely challenging and fragile environment.

Finally, when writing the rule, BSEE consulted with a number of agencies, including the USCG and the EPA. Moreover, Federal agencies communicate on a regular basis about issues over which they have intersecting authority. Thus, once this rule is in place, BSEE will continue to communicate with other agencies to maximize efficiencies and minimize or eliminate potential conflicts.

Two commenters noted the importance of setting limits on the continued drilling of any well relying on a particular SCCE if a blowout occurs in connection with another operation relying on the same SCCE as a result of mutual aid agreements or cooperatives formed to share SCCE. The commenters note that similar mutual aid agreements and cooperatives have already been formed by Arctic operators to share spill response resources, well capping equipment, and facilities. The commenter provides the example that, if four wells are being drilled and all four rely on the same SCCE package, if one well has a blowout then the other three wells should be suspended and safely secured while the SCCE is committed to the blowout response.

BSEE agrees with the commenter and concludes that this issue is addressed in the performance standard finalized at § 250.471(a), as incorporated into the operator's approved EP (§ 550.220(c)(3)) and APD (§ 250.470(f)). An operator is required to have access to the appropriate SCCE positioned to ensure it will arrive at the well location within a prescribed time limit. This may necessitate halting continued drilling at other well locations if the equipment is being used at the site of the spill in a manner that would preclude the equipment from being accessible for use in a potential well control event at the other well location within the prescribed time limits.

One commenter suggests the final rule should adequately describe technical findings or actual application success rates of containment dome systems used in OCS waters of less than 300 feet, which is commonly found in Alaska's near shore and OCS waters. The commenter questioned whether containment domes have ever safely been deployed in shallow water under a jack-up rig, where leg placement may present hazards when setting the containment dome.

BSEE notes that there has been no need to deploy a containment dome since the Macondo Well blowout in April of 2010.[35] Containment domes have been proposed for Arctic shallow water operations and have been successfully deployed and function tested on multiple occasions. A containment dome is intended to minimize or eliminate the release of oil to the environment in the event that the capping stack or the cap and flow system does not stop an uncontrolled flow. The use of a containment dome is the only tool proposed by an operator to date that has been shown to contain the flow of a well until the well bridges off or the relief well is finished and the well is plugged. BSEE again notes the revision to § 250.471(i) clarifying the performance standard an operator may show for approval of alternative procedures. BSEE may approve innovative methods to contain the flow of oil, in the event that a capping stack, cap and flow system, containment dome or other method of subsea intervention has failed to stop an uncontrolled flow (because of damage to the wellhead, equipment failure, or some other reason), until the relief well can be completed. This performance-based equivalency allows BSEE the flexibility to evaluate well control and containment equipment and devices that may be developed and deployed in the future.

One commenter suggests that BSEE remove the statement indicating that BSEE will direct any emergency response operations, reasoning that it fails to consider interfaces with the current role of the USCG.

BSEE disagrees with removing this statement. As previously described, OCSLA requires that BSEE ensure that OCS oil and gas operations minimize damage to the environment and conserve the natural resources of the OCS. Under OCSLA, BSEE also ensures that OCS oil and gas operations do not result in pollution, create hazardous or unsafe conditions, or unreasonably interfere with other uses of the area.

The deployment of SCCE is a well control measure designed to maintain, or regain, control over a subsea well. The deployment of SCCE will permit an operator to ensure the integrity of an OCS wellbore and maintain control over well pressure and well fluids. For example, a timely deployed capping stack will prevent the release of fluids into the environment in the cap and flow mode. Maintaining or regaining this type of well control ultimately promotes OCS safety, protects the environment, and conserves the natural resources of the OCS. Thus, these regulations implement OCSLA's authorization for BSEE to prescribe regulations concerning oil and gas operations on the OCS.

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[34] See, *e.g.*, 43 U.S.C. 1332(3), 1332(6), 1334(a), 1340(g), 1348(b).

[35] After the blowout at the Macondo well on April 20, 2010, the out-of-control well flowed for 87 days until a capping stack was installed on July 12, 2010. On July 15, 2010, it was determined that the flow from the well had stopped. Permanently killing the well required the drilling of a relief well, which was completed on September 16, 2010.

In addition to this OCSLA authority, the President delegated to the Secretary the OPA authority under CWA Section 311(j)(1)(C) concerning "establishing procedures, methods, and equipment and other requirements for equipment to prevent and to contain discharges of oil and hazardous substances from . . . offshore facilities, including associated pipelines . . . ."[36] These regulations, including those regarding SCCE, implement the Secretary's OPA authority with respect to equipment, procedures, and methods that prevent and contain oil discharges from offshore facilities.

BSEE's process for interfacing with the USCG with respect to directing well control measures from offshore facilities during a well control event is clearly described and has been carefully coordinated in BSEE/USCG MOA: OCS–03, *Oil Discharge Planning, Preparedness, and Response* (April 3, 2012). MOA: OCS–03 states "the Regional Supervisor or designated individual will direct measures to abate (stop and/or minimize) sources of pollution from BSEE-regulated offshore facilities to ensure minimal release of oil and to prevent unwarranted shutdown of unaffected production and pipeline systems. However, if an oil discharge poses a serious threat to public health, welfare, or the environment, in accordance with [OPA], the Federal on Scene Coordinator (FOSC) may take action for effective and immediate removal of a discharge and to ensure mitigation or prevention of a substantial threat of a discharge of oil." The description of this inter-agency process is ultimately consistent with the National Oil and Hazardous Substances Pollution Contingency Plan's (NCP) requirement that "[r]esponse actions to remove discharges originating from operations conducted subject to [OCSLA] [must] be in accordance with the NCP."[37] It is also consistent with the NCP that vests in the EPA or USCG On-Scene Coordinator the authority to direct all spill response actions. (40 CFR 300.135). Notwithstanding the NCP's clear establishment of OSC authority with respect to directing spill response actions, OPA and the NCP do not generally preempt all other relevant legal authorities. As EPA explained in 1994: "Section 311(c)(1) of the CWA, as amended by the OPA, gives the OSC authority to 'direct or monitor all Federal, State, and private actions to remove a discharge.' . . . Congress explicitly provided for limited preemption only for contracting and employment laws and this limited preemption applies only when a discharge poses a substantial threat to the public health or welfare of the U.S. There is no express indication that Congress intended to preempt all Federal and State requirements with respect to other discharges."[38] BSEE's authority concerning SCCE is consistent with the complementary nature of the NCP in that the OSC has the authority to direct and monitor spill response actions while not preempting all other relevant legal authorities.

One commenter recommended the final rule include a provision requiring the operator to submit an SCCE Emergency Plan as part of the part 550 EP, subject to the public review requirements. The commenter suggests that the SCCE Emergency Plan should include various information, including: The technical and operating specifications of the equipment; standard operating procedures and schedules for testing, operation, inspection, maintenance and repair; and plans for storage, transportation to the well, and deployment. The commenter asserted that written plans provide consistent standard operating procedures for company staff that change over time, provide an excellent reference during an emergency response, and serve as an excellent training tool.

BOEM and BSEE agree with the commenter on the importance of awareness of SCCE assets and response capabilities and planning for their maintenance, deployment, and use. However we do not agree with the need for a specialized SCCE Emergency Plan as part of an operator's EP. Paragraphs (a) and (c) of § 550.220 already require that an operator's EP describe their emergency plans to respond to a fire, explosion, personnel evacuation, or loss of well control, among other things, as well as provide a general description of the operator's SCCE capabilities. The finalized provisions of §§ 250.471 and 250.470(f) also provide for sufficient BSEE oversight of the operator's SCCE capabilities to account for any staff changes over time, including requirements for the operator to: Detail the SCCE and the contractor's SCCE capabilities, include descriptions of all SCCE, and describe procedures for inspection/testing of SCCE.

Paragraph (a), Drilling Below or Working Below the Surface Casing

Paragraph (a) requires that the operator, when using a MODU to drill below or work below the surface casing, have access to a capping stack positioned to arrive at the well within 24 hours after a loss of well control, and a cap and flow system and a containment dome positioned to arrive at the well within 7 days after a loss of well control.

Several commenters recommend that the cap-and-flow system and containment dome should be required to arrive within three days, as the quicker the cap-and-flow system and containment dome are available and on-site, the faster any blowout may be controlled.

BSEE appreciates the commenters' concern for rapid deployment of the cap-and-flow system and containment dome as a means to control any blowout as quickly as possible, and encourages operators to deploy source control and containment assets without undue delay. However, BSEE has decided to finalize this provision with the 7-day timeframe for arrival after the loss of well control. The 7-day timeframe allows for the appropriate arrival of all the SCCE response equipment and responders and facilitates a staged response during the early hours of an event. The cap-and-flow system and containment dome are elements of a systematic approach to the SCCE deployment, and the 7-day requirement provides for the arrival of the system after the operator has had time to deploy and test the capping stack and to complete other more immediate intervention options.

Several commenters recommend BSEE not impose timeframes for the deployment of SCCE and instead allow for performance-based requirements using a risk-based approach. One commenter suggests that the positioning of SCCE assets be determined on a case-by-case basis that takes into account any unique aspects of an operator's program and the well site, and that these tailored mobilization and operational timelines would be best captured in an operator's EP. Another of the commenters specifically urges consideration of the merits of a bottom-founded rig with a pre-installed capping device, which can cap a well in a matter of minutes or hours.

We note the final rule does not prohibit the use of pre-positioned capping stacks when operating a jack-up rig. To clarify this, we have added text to explicitly add a pre-positioned capping stack to the definition of

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[36] Executive Order 12777, sec. 2(b)(3), 56 FR 54757 (Oct. 18, 1991).

[37] 40 CFR 300.125(e).

[38] 1994 final revisions to NCP, 59 FR 47389–90 (Sept. 15, 1994).

"Capping Stack" in § 250.105. We also note that § 550.220(c)(3) does contemplate a description of the operator's SCCE capabilities and plans for compliance in the EP.

In response to commenters' request for a revised timeframe determined either by the use of a pre-positioned capping stack or on a case-by-case basis, BSEE has determined the requirements of this section appropriately implement a coordinated redundant system to provide adequate safety, and declines to modify the rule as suggested. The timeframes implemented in § 250.471 establish a sequential process based on operator proposals for dealing with Arctic challenges in a risk-based manner. In the event of a well control incident, the first option is to deploy a capping stack. The capping stack is the most immediately deployable of the SCCE options. If the capping stack is not successful, the cap and flow system is the next option. If these options are not deployable, or fail to stop the flow, the containment system must be deployed to contain the flow from the well during the time it takes the well to bridge off or the relief well to be drilled. Each of these options has a high probability of success, but none is guaranteed to be deployable or successful in all situations. The redundancy and sequencing of the responses, based on the time necessary to deploy and the increasing complexity, provides sufficient safety in a reasonable and appropriate framework. The 7-day timeframe for deployment of SCCE is the maximum timeframe allowed and, if an operator can deploy appropriate equipment in under 7 days, that is permissible and encouraged to the extent it may enhance the response. If an operator determines alternate procedures or equipment will provide for equal or better levels of protection, as discussed earlier, an operator may submit a request under existing § 250.141, and such procedures may be approved on a case-by-case basis.

Several commenters oppose the specific requirement for timely access to a containment dome, asserting that a performance-based requirement would be more appropriate. Commenters assert that a containment dome poses serious problems and risks in shallow water, and may only be compatible with a narrow range of drilling approaches. One commenter argued that future and existing technologies, including subsea shut-in devices, are being pursued to provide better outcomes in the highly unlikely event of a well control incident in Arctic conditions, and that there is no sound technical basis for including a containment dome as a specific requirement.

BSEE disagrees. The containment dome is intended to immediately contain oil that would otherwise be discharged into the environment in the event that the capping stack or any other method of subsea intervention does not stop an uncontrolled flow. The use of a containment dome is the only tool proposed by an operator to date that has been shown to contain the flow of a well following failure of such control interventions until the well bridges off or the relief well is finished and the well is plugged. As described above, § 250.141 and this final rule at § 250.471(i) allows for the District Manager or Regional Supervisor to approve the use of alternate procedures or equipment provided the operator can show the technology will meet or exceed the level of safety and environmental protection provided by the containment dome. The rule, therefore, specifically provides that BSEE may approve innovative methods to contain the flow of oil, in the event that a capping stack or other method of subsea intervention has failed to stop an uncontrolled flow (because of damage to the wellhead, equipment failure, or some other reason), until the relief well can be completed. This performance-based equivalency allows BSEE the flexibility to evaluate well control and containment equipment and devices that may be developed and deployed in the future.

One commenter requested that, if BSEE does not eliminate the containment dome requirement entirely, the regulations should specify that, when a jack-up rig is used with a subsurface BOP and a prepositioned capping device, a containment dome is not required. The commenter also asserted that the use of a well design using full pressure containment in the wellbore addresses and minimizes the risk of "broaching" (the escape of hydrocarbons through the cement occupying the space between the wellbore and the strata outside the casing) precluding the need for any kind of additional well containment, such as a cap and flow system. The commenter asserted that the combination of a jack-up rig, a prepositioned capping device, and a Level 1 well design materially strengthens spill prevention by adapting proven technologies to the Arctic context, and results in unique advantages with respect to spill prevention such as full pressure containment to the rig floor, access to a surface BOP, and a preinstalled cap with a response time of mere minutes.

BSEE disagrees with removing the requirement for a containment dome. Although the commenter refers to a "prepositioned capping device", we assume the reference is to a prepositioned capping stack. As discussed previously in this Section, the SCCE requirements are intended to ensure that operators have a coordinated and redundant system to provide for adequate safety in exploratory drilling operations on the Arctic OCS. The capping stack must be positioned to arrive at the well location within 24 hours after loss of well control. If the out-of-control well is not successfully stopped by the capping stack, the other SCCE must arrive at the well location within 7 days after a loss of well control or as directed by the Regional Supervisor. The containment dome is intended to immediately contain oil that would otherwise be discharged into the environment in the event that the capping stack or any other method of subsea intervention does not stop an uncontrolled flow. The containment dome and cap and flow system are part of a sequential process based on operator proposals for dealing with Arctic challenges in a risked based manner. Therefore, removing the containment dome from the sequential approach would negate the intent of the requirements.

Regarding the commenter's suggestion of utilizing a pre-positioned capping stack, we do agree this may be appropriate in specific situations. BSEE notes that this final rule does not preclude the use of a prepositioned capping stack as a part of an operator's proposal. To clarify this, we have revised the definition of Capping Stack to specifically include pre-positioned capping stacks, which may be utilized below subsea BOPs when deemed technically and operationally appropriate, such as when using a jack-up rig with surface trees.

One commenter asserted that the safety and technical issues presented by installing a containment dome between the legs of a bottom-founded rig are sufficient to dismiss the use of a containment dome out of hand in most situations.

BSEE disagrees. This comment assumes that the rig will not have been moved off the location in the event of a loss of well control that has continued for the amount of time it would take to deploy a containment dome (up to seven days under this rule). If the well control event requires that the rig move off location, the containment dome would not only be viable, but necessary to contain the flow during relief well operations. When one considers that the drilling floor on modern jack-ups is cantilevered off one side of the rig, the premise that the containment system must operate "between the legs" also does not follow. Additionally, as discussed earlier, an operator may request to use alternate procedures or equipment under existing § 250.141 and this final rule at § 250.471(i).

Paragraph (b), Stump Test

Paragraph (b) requires monthly stump tests of dry-stored capping stacks, and stump tests prior to installation for pre-positioned capping stacks. The finalized provision imposes a requirement that any capping stack that is dry stored must be stump tested (function and pressure tested to prescribed minimum and maximum pressures on the deck in a stand or stump where it could be visually observed) monthly. The final rule also requires that pre-positioned capping stacks be tested prior to each installation on a well to assure BSEE that no damage was done during the prior deployment or transit.

One commenter recommended that any testing requirements of capping stacks and similar equipment not add to testing requirements in other OCS regions. The commenter asserted that there is no rationale to change these standards for Arctic conditions, and instead suggests revisions to allow for the operator to demonstrate that the SCCE (including elastomers and hydraulic control fluid) are suitable for the expected specific operating environment, including both surface and subsea conditions.

Although it is unclear from the comment what "similar equipment" testing requirements the commenter is referencing, BSEE disagrees with the recommendation to align stump testing requirements for Arctic OCS capping stacks with those applicable to other OCS regions. The harsh conditions on the Arctic OCS do justify enhanced regulatory requirements for testing and maintaining equipment, and therefore BSEE has determined that more rigorous stump testing of capping stacks is appropriate. BSEE agrees with the commenter that requirements should be in place to ensure an operator can demonstrate that the SCCE is suitable for the expected operating environment. Accordingly, multiple provisions finalized in this rulemaking require such a demonstration. See, *e.g.,* § 250.473(a) (establishing the requirement that equipment and materials (including elastomers and fluids) to be rated or de-rated for service under conditions that can be reasonably expected during operations); § 250.470(a)(2) (requiring a detailed description of how equipment will be prepared for service in the relevant conditions); § 250.470(f) (requiring a detailed description of SCCE capabilities under Arctic OCS conditions); § 550.220(c) (requiring descriptions in the EP of the suitability of an operator's planned activities and capabilities for Arctic OCS conditions).

Paragraph (c), Reevaluating SCCE for Well Design Changes

Paragraph (c) requires a reevaluation of the SCCE capabilities if the well design changes because some well design changes may impact the WCD rate. If the operator proposes a change to a well design that impacts the WCD rate, the operator must provide the new WCD rate through an Application for Permit to Modify (APM), as required by existing § 250.465(a). The operator must then verify that the SCCE would either be modified to address the new rate or that the previously proposed system would be adequate to handle the new WCD to demonstrate ongoing compliance with the SCCE capability requirements previously addressed.

No comments were received on the proposed addition of this section and the section is therefore finalized as proposed.

Paragraph (d), SCCE Tests or Exercises

Paragraph (d) requires the operator to conduct tests or exercises of the SCCE, including deployment of the SCCE, when directed by the Regional Supervisor. Similar to the requirement that equipment be tested periodically, BSEE has concluded that there is a need to ensure that personnel are prepared and that they, and the SCCE, would be capable of performing as intended. Therefore, BSEE is requiring that operators conduct tests and exercises (including deployment), at the direction of the Regional Supervisor, to verify the functionality of the systems and the training of the personnel.

Three commenters requested § 250.471(d) establish minimum testing requirements and that BSEE provide more specific details as to the timing and number of tests and exercises. The commenters recommend that SCCE be tested prior to each drilling season to ensure it is functioning properly and capable of working effectively during an emergency, and that the equipment be exercised at least once during the drilling season to ensure personnel have the opportunity to practice deployment and use of this critical well control equipment in Arctic conditions. One of the commenters recommended testing or exercises be conducted prior to active operations at a scheduled time so that required trained personnel can participate, and to enable adequate planning. The commenter suggests that, to ensure all required resources will be available at the agreed time, the date for any tests or exercises should be agreed to a minimum of 180 days in advance.

BSEE disagrees with requiring a prescribed frequency of testing of SCCE equipment or with pre-arranging all tests well in advance. The testing requirements in this final rule are the result of balancing logistics and safety concerns against the need to maintain the relevant systems in a constant state of readiness. Placing strictly pre-defined parameters on testing would allow for a level of staging and preparation that is not realistically reflective of the real-world scenarios in which the relevant capabilities would be needed. The Regional Supervisor should be allowed to determine the appropriate balance on a case-by-case basis. The SCCE equipment is not directly involved in drilling and, as such, the required state of readiness and availability can only be attained by testing as proposed, which allows for a case-by-case flexibility.

One commenter recommended testing the SCCE in Arctic OCS conditions at the exploration drill site during the drilling season.

BSEE has determined the logistics of testing at the Arctic OCS site introduce more risk than such testing would alleviate. One example of the types of difficulties of onsite testing in Arctic OCS conditions is that it is currently not feasible to transport to the Arctic the large volume of nitrogen that is required for recharging equipment. Nitrogen recharging of the surface SCCE equipment is used to help control corrosion during deployment and also helps minimize the risk of explosion, should use of the equipment become necessary. Recharging the system also helps monitor the system for leaks. Because recharging cannot currently be accomplished onsite, in the Arctic, it is more prudent to conduct testing and accomplish recharging outside the Arctic, where the nitrogen charges can be transported. This approach helps to ensure that the SCEE equipment will be properly charged and will be capable in the unlikely event that it is needed to response to a well control event during operations.

Paragraphs (e) and (f), SCCE Records Maintenance

Paragraph (e) requires the operator to maintain records pertaining to testing, inspection, and maintenance of the SCCE for at least 10 years, and make them available to BSEE upon request. This information will facilitate a review of the effectiveness of the operator's inspection and maintenance procedures and provide a basis of review for performance during any drill, test, or necessary deployment. A 10-year record retention requirement is necessary to ensure enough cumulative data is gathered to assess overall equipment performance and trends.

Paragraph (f) requires the operator to maintain records pertaining to use of the SCCE during testing, training, and deployment activities for at least 3 years and make them available to BSEE upon request. The use of the equipment during testing and training activities and actual operations must be recorded, along with any deficiencies or failures. These records will allow BSEE to address any issues arising during the usage and to document any trends or time-dependent problems that would develop over the record retention period. In the event that the equipment is used in a well control incident, the records are necessary to document the effectiveness of the response and functioning of the equipment.

Two commenters recommend that all records be retained for a consistent period and electronically submitted to BSEE, unless BSEE can explain the reason for recommending a different record retention schedule.

BSEE disagrees. The record maintenance requirements are intended to mirror current regulations to the extent possible given the long lead times and down periods in Arctic exploratory drilling. *See* §§ 250.426, 250.434, 250.450 and 250.467. BSEE has determined electronic submission should remain an option, not a requirement.

Paragraphs (g) and (h), Mobilizing and Deploying SCCE

Paragraph (g) requires operators to initiate transit of SCCE to a well immediately upon a loss of well control. Paragraph (h) requires that operators deploy and use SCCE when directed to do so by the Regional Supervisor. This provision ensures that all SCCE is available and ready for use and reinforces the Regional Supervisor's authority and discretion to require the deployment and use of SCCE in the event of a loss of well control.

One commenter suggests revising these sections to indicate that the Regional Supervisor must consult with the FOSC (and State on Scene Coordinator (SOSC) in state waters, and appropriate stakeholders and technical experts regarding the deployment of SCCE. The commenter expressed concern that the proposed requirements of § 250.471(h) indicate that the Regional Supervisor has the full authority to require the deployment of the capping stack and cap and flow system, without any requirement to consult with the Regional Response Team, the FOSC, or any technical experts. The commenter asserted that, under Federal law, the FOSC is in charge of oil spill response and is the sole Federal entity authorized to require actions to control a potential discharge. Another commenter further recommended that §§ 250.471(g) and (h), and § 250.472(a) should be eliminated or expressly subordinated to direction from the FOSC through the Incident Command System (ICS). The commenter alternately suggests that, if this recommendation is not accepted, BSEE should revise the provision to clarify that any direction to deploy or use SCCE or a relief rig by the Regional Supervisor must be requested within the Unified Command.

BSEE is aware that through OPA and the NCP, "[t]he OSC in every case retains the authority to direct the spill response, and must direct responses to spills that pose a substantial threat to the public health or welfare of the United States." (59 FR 47384, 47387 (Sept. 15, 2016)). In this context, BSEE will continue to consult with the USCG as the on scene coordinator with the authority to direct and monitor spill response actions under the NCP. Notwithstanding, BSEE recognizes that OPA and the NCP do not expressly preempt all other relevant legal authorities that may be implicated during a spill response. (59 FR 47389–90 (Sept. 15, 1994)). The final rule's requirement that an operator deploy and use SCCE when directed by the Regional Supervisor in § 250.471(h) is consistent with BSEE's OCSLA authorities concerning the regulation of oil and gas exploration activities on the OCS. Neither OPA nor the NCP preempts BSEE's regulatory authority with respect to the regulation of these activities. Additionally, as discussed above, in addition to this OCSLA authority, the President delegated to the Secretary the OPA authority under CWA Section 311(j)(1)(C) concerning "establishing procedures, methods, and equipment and other requirements for equipment to prevent and to contain discharges of oil and hazardous substances from . . . offshore facilities, including associated pipelines . . ." These regulations, including those regarding SCCE, implement the Secretary's OPA authority with respect to equipment, procedures, and methods that prevent and contain oil discharges from offshore facilities.

The BSEE Regional Supervisor has both the technical expertise for source control operations and the authority to require the operator to implement SCCE measures under OCSLA. MOA:OCS–03 describes the roles of BSEE and the USCG during responses to spills from offshore facilities: "In the event of an oil discharge or substantial threat of an oil discharge from an offshore facility seaward of the coastline, BSEE has primary responsibility for monitoring and directing all efforts related to securing the source of the discharge and reestablishing source control . . . the Regional Supervisor or designated individual will direct measures to abate sources of pollution from regulated offshore facilities to ensure minimal release of oil and to prevent unwarranted shutdown of unaffected production and pipeline systems." Both BSEE and the USCG acknowledge the need to seamlessly coordinate source control and other oil spill response activities. BSEE and the USCG established the position of the Source Control Support Coordinator (SCSC) within ICS framework and the 2014 edition of the USCG Incident Management Handbook (IMH). As provided for in the USCG IMH, "the SCSC . . . is the principal advisor to the FOSC for source control issues. The SCSC serves on the FOSC's staff and is responsible for providing source control support for operational decisions and for coordinating on-scene source control activity. During a source control issue involving a loss of well control or pipeline incident on the OCS, the SCSC and other source control technical specialists are provided by BSEE." As such, there are clear policies in place and already agreed to between the USCG and BSEE regarding how source control activities resulting from a loss of well control should be implemented and how they should be addressed within ICS and the Unified Command. The provisions within this rulemaking are consistent with all existing statutory authorities, MOA:OCS–03, and the USCG's ICS framework within the IMH.

One commenter recommended that BSEE link the SCCE requirements to the operator's approved Emergency Response Plan such that, in the event of a loss of well control, the primary SCCE will be mobilized in accordance with the operator's approved Emergency Response Plan. The commenter also recommended that, during the transit of the primary SCCE, the operator will administer secondary intervention measures per their response plans to terminate or minimize the flow of hydrocarbon to the seafloor. The commenter also requested additional clarification of BSEE's level of responsibility, accountability and liability in the event of any incidents that occur as a result of the operator complying with the requirements of § 250.471(g), pursuant to which the operator must deploy and use SCCE when directed by the Regional Supervisor.

This provision is intended to emphasize that the purpose of the SCCE requirement is to ensure that the operator is able to quickly commence source control operations, and BSEE does not agree that the suggested revisions are needed. The timeframes finalized in § 250.471 are minimum planning standards and may become relevant well before the ICS is activated and an Emergency Response Plan comes into play. This is also especially important with respect to the beginning of relief well operations under § 250.472.

Regarding the comment on BSEE's associated responsibility, accountability, and liability if § 250.471 requirements are invoked, BSEE clarifies that we do not propose to assume control over any operations. The finalized provisions of this rulemaking simply require the operator to comply with the terms of the regulations and its approved plans and permits and discuss BSEE's authority to order such compliance. The operator is responsible for safely executing all operations in compliance with the regulations and its approved plans and permits. BSEE has no authority to offer advisory opinions concerning the scope of potential executive agency legal liability. BSEE is authorized to prescribe rules and regulations that are necessary to carry out the provisions of OCSLA. (43 U.S.C. 1334(a)). Questions concerning legal liability are beyond the scope of this rulemaking and BSEE makes no representations concerning legal liability in this rule.

Paragraph (i), Approval of Alternative Compliance Measures

As discussed in Section IV.A, *Summary of Key Changes from the NPRM,* in response to comments BSEE is adding a paragraph (i) to clarify when an operator is requesting approval of alternate compliance measures to the SCCE requirements under the provisions of § 250.141 and this final rule, the operator should demonstrate that the proposed alternate compliance measure provides a level of safety and environmental protection that meets or exceeds that required by BSEE regulations, including demonstrating that the alternate compliance measure will be capable of stopping or capturing the flow of an out-of-control well. These revisions are in response to commenters' concerns that the language as originally proposed did not clearly state a performance standard.

What are the relief rig requirements for the Arctic OCS? (§ 250.472)

BSEE proposed to add a new § 250.472 which requires an operator to have available a relief rig when drilling below or working below the surface casing. The provisions also proposed to establish a 45-day maximum limit on the time necessary to complete relief well operations. BSEE notes the relief rig could be stored in harbor, staged idle offshore, or actively working, as long as it would be capable of physically and contractually meeting the proposed 45-day maximum timeframe. However, any relief rig must be a separate and distinct rig from the primary drilling rig to account for the possibility that the primary rig could be destroyed or incapacitated during the loss of well control incident.

Many commenters expressed general support for the relief rig requirements. Many other commenters suggested various revisions to this section. As discussed in Section IV.A, *Summary of Key Changes from the NPRM,* BSEE is revising the language of this section in response to comments to clarify the performance standard that must be met when proposing to use alternate equipment or procedures to the relief rig requirements of § 250.472. Specifically, we are adding the phrase "able to kill and permanently plug an out-of-control well" to the proposed § 250.472(a) to clearly state the performance standards the relief rig must achieve. We are also revising the proposed § 250.472(c) to clarify when an operator is requesting approval of alternate compliance measures to the relief rig requirements under the provisions of § 250.141 and this final rule, the operator will need to demonstrate that the proposed alternate compliance measure provides a level of safety and environmental protection that meets or exceeds that required by BSEE regulations, including demonstrating that the alternate compliance measure will be able to kill and permanently plug an out-of-control well. These revisions are in response to commenters' requests for a clear statement of a performance standard and are designed to offer guidance and clarification to operators with respect to the performance-based standard established by this rule that any proposed alternate compliance must meet or exceed. All other provisions of § 250.472 are finalized as proposed for the reasons discussed herein.

Several commenters recommended that BSEE remove the relief rig requirements and revise the final regulations to implement a performance-based equipment requirement. Commenters suggest that the availability of several alternative technologies, such as capping stacks, prepositioned capping devices, and subsea isolation devices (SID), negate the need to require a relief rig.

BSEE disagrees with the suggestion to remove the relief rig requirement. We have determined that a relief rig is currently the most reliable option for permanently killing and plugging an out-of-control well. We do agree with the commenters' concerns that the regulations provide flexibility and allow for the use of new technology that can meet or exceed the level of safety and environmental protection provided by a relief rig in the event of an out-of-control well. None of the types of technology proposed by the commenters, however, have been proven to be conclusively, and consistently, effective at killing and permanently plugging an out-of-control well. Therefore, BSEE has determined to finalize the § 250.472 requirement for an operator to have appropriate access to a relief rig, different from the primary drilling rig, when drilling or working below the surface casing during Arctic OCS exploratory drilling operations.

Although a relief well is the most reliable, and in some circumstances the only available, solution to kill and permanently plug an out-of-control well, there may be circumstances where innovative alternative compliance measures to drilling a relief well are available. The proposed § 250.472(c) addressed this concern by directing operators to existing § 250.141, *May I ever use alternative procedures or equipment?*. In response to comments, we have revised § 250.472(a) to include a more explicit performance standard, where the relief rig must be able to "kill and permanently plug an out-of-control well". We have also revised the language of proposed § 250.472(c) as set out in the regulatory text at the end of this document.

Many comments also requested additional clarity and explicit procedures for an operator to apply for the use of equivalent technology.

BSEE understands the commenters' stated reasons for desiring additional details about how to obtain approval for alternative procedures or equipment under § 250.141 and this final rule. As discussed in Section III.B and D of this preamble, operators may request approval for innovative technological advancements that may provide them additional flexibility, provided that the operator can establish that such technology provides at least the same level of protection as the relief rig requirements.

One commenter asserted that the requirement for a relief rig under § 250.472 is in conflict with the preference for performance-based regulations established in E.O. 12866, E.O. 13563 and associated guidance.

BSEE disagrees. Section 250.472 is consistent with the relevant portions of E.O. 12866, E.O. 13563 and the associated Office of Information and Regulatory Affairs (OIRA) guidance because it would allow for operators to utilize less expensive technologies that achieve the performance outcome of permanently killing and plugging an out-of-control well in a timely fashion. Importantly, within certain general parameters, the proposed regulation leaves a fair amount of discretion with the operator as to how to accomplish that outcome. Although this provision presumptively requires that operators have access to relief rigs to achieve the regulatory outcome, it sets forth the minimum level of prescription necessary to achieve the end, leaving many performance-based options available for operators to pursue. Additionally, § 250.472(c) expressly permits operators to propose alternate equipment to achieve the regulatory objective of permanently killing and plugging an out-of-control well. We note that we considered at the NPRM stage imposing more prescriptive requirements for relief rig capabilities, but instead chose to provide operators flexibility by selecting the best approach that would accomplish the ultimate goals.[39]

Many commenters expressed their support for the NPC Arctic Potential Study and suggest we revise the relief well requirements to align with the Study's findings. The commenters cite to the NPC Arctic Potential Study's suggestion of alternative preventative measures such as well design, capping stacks or subsea shutoff devices as methods of spill mitigation and containment.

BSEE disagrees with the recommendation to revise § 250.472 and does not view the requirements finalized in this rulemaking as being in conflict with the NPC Arctic Potential Study. As discussed in Section IV.B.1, *General Comments,* BOEM and BSEE recognize the NPC Arctic Potential Study as a valuable comprehensive study that considers the research and technology opportunities to enable prudent development of U.S. Arctic oil and gas resources. However, it is only one of the resources our regulatory experts considered in developing regulations to ensure the safe and responsible development of petroleum resources on the Arctic OCS. BSEE has determined that the relief rig requirements are appropriate to ensure the operator is able to kill and permanently plug an out-of-control well in a reasonable and safe amount of time. Additionally, the finalized provisions of § 250.472 align with the NPC Arctic Potential Study's recommendations for the availability of alternate technology to a relief rig. We note that operators generally do not view relief wells as the preferred alternative in a well control event. As reflected in § 250.471 and throughout its existing source control regulations, BSEE, too, does not view a relief well as a first-choice well intervention. Although a relief rig is the primary technology for killing and permanently plugging an out-of-control well, it is intended to be a part of the continuum of response, beginning with the source control and containment intervention measures. However, in the Arctic, due to the very short portion of the year in which well locations are accessible, BSEE has determined that timely access to a relief rig is an appropriate requirement to ensure the lowest risk of a prolonged uncontrolled flow under the ice, which will cover the site for a majority of the year. BSEE has not identified an alternative technology that provides the same level of reliability for permanently killing and plugging an out-of-control well following attempts, successful or unsuccessful, to achieve temporary control through more direct intervention options. An operator may always request approval of alternate equipment or procedures under § 250.141 and this final rule, as appropriate. These alternative compliance measures may be approved if they are shown to meet or exceed the level of safety and environmental protection provided by the relief rig requirements of § 250.472.

Two commenters opposed the use of any equipment performance standard in this provision, asserting that the requirement for a relief rig should be mandatory. The commenters assert that permitting the use of any alternative compliance measures would necessitate a formal rulemaking with public notice and comment.

BSEE recognizes the commenters' concern, but disagrees with precluding the use of any alternative procedures or equipment to the relief rig requirements of § 250.472. We note that the ability of industry to innovate within regulatory constraints requires a careful balance, especially when undertaken in environmentally sensitive areas such as the Arctic OCS. In attempting to strike this balance, we have determined the hybrid prescriptive and performance-based requirements of § 250.472 are appropriate. Further, no additional formal rulemaking is necessary because an operator's option to apply for the use of alternate compliance measures is always available for any of the part 250 regulations under the existing regulatory provisions previously promulgated through notice and comment procedures at § 250.141.

Two commenters asserted that the relief well requirement is not best available and safest technology (BAST) as required by OCSLA at 43 U.S.C. 1347(b).[40] One of the commenters asserted that BAST for source control is a capping stack, not a relief well, because drilling a same season relief well takes significantly longer to control a source than does the deployment of a capping stack, and the risk profile associated with drilling a same season relief well is greater than that associated with a capping stack. Several commenters cite two Minerals Management Service (MMS) studies[41] as supporting the assertion that relief rigs are not an effective means to kill and permanently plug an out-of-control well and therefore should not be included in regulatory requirements.

BSEE disagrees with the commenters. We determined that there is adequate support for requiring a relief rig for Arctic OCS exploratory drilling operations. BSEE has concluded that the requirement to have access to and utilize a relief rig to kill and permanently plug an out-of-control well is necessary and appropriate under Arctic OCS conditions. Although the commenters point to the MMS Studies as countering this conclusion, the MMS studies examined blowouts only occurring on the Gulf of Mexico OCS, with the exception of one on the Pacific OCS. As discussed throughout this final rule, the Arctic OCS is a uniquely challenging operating environment. In the Arctic, exploratory drilling operations from MODUs occur only during the open water season, in a region with little or no infrastructure that is subject to variable and sometimes extreme weather, and where transportation systems could be interrupted for significant periods. Additionally, if a blowout occurs during the open water season, it is imperative to permanently kill and plug the well in as short a time as possible, as ice encroachment may complicate or prevent drilling and transit operations and preclude a resolution of the situation before the extended off-season.

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[39] 80 FR 9940.

[40] The Secretary of Interior "shall require, on all new drilling and production operations and whenever practicable, on existing operations, the use of the best available and safest technologies (BAST) which the Secretary determines to be economically feasible, wherever failure of equipment would have a significant effect on safety, health, or the environment, except where the Secretary determines that the incremental benefits are clearly insufficient to justify the incremental costs of utilizing such technologies."

[41] Izon, David, Danenberger, E.P., and Mayes, Melinda, "Absence of Fatalities in Blowouts Encouraging in MMS Study of OCS Incidents 1992–2006", Drilling Contractor magazine, pages 84–90, July/August 2007; Danenberger, E.P., "Outer Continental Shelf Drilling Blowouts, 1971–1991", OTC #7248, 25th Annual Offshore Technology Conference, Houston, Texas, May 1993.

Commenters also appear to misconstrue the nature of the relief rig requirements, particularly their connection with the SCCE requirements of § 250.471. Commenters emphasize the preference for using capping stacks to regain prompt and immediate control of an out-of-control well. BSEE agrees with this assertion, as reflected in the provisions of § 250.471 requiring Arctic OCS operators to have a capping stack stationed nearby for prompt deployment to an out-of-control well as an initial response. BSEE acknowledges the timelines and challenges that accompany relief well operations, particularly on the Arctic OCS. BSEE does not propose the relief rig as an alternative to the capping stack, but rather as a supplement to the capping stack serving the distinct purpose of permanently killing and plugging the well. While capping stacks are sometimes—though not always—capable of regaining immediate control over a well, BSEE believes that the best available option to kill a well reliably and permanently, and to allow for safe longer-term abandonment, is a relief well. Accordingly, a relief rig is not an alternative to a capping stack, but rather a separate line of defense in the event of its failure, and/or the most reliable method for shifting from the temporary control potentially provided by a capping stack to the permanent killing of an out-of-control well on the Arctic OCS. Additionally, as discussed previously, operators may utilize alternate equipment or procedures if they can show the alternate compliance measures meet or exceed the level of safety and environmental protection provided by a relief rig. Specifically, the alternate compliance measure must demonstrate the ability to kill and plug an out-of-control well permanently; separate and distinct from the potential immediate well control capabilities of a capping stack.

BSEE notes that, under § 250.107(c), it presumes that an operator's compliance with BSEE regulations constitutes BAST. BSEE's Office of Offshore Regulatory Programs is responsible for developing and maintaining regulations, policies, standards and guidelines related to BAST. We continuously strive, through programs, such as the Technology Assessment Program, and collaborations, such as the Ocean Energy Safety Institute, to identify and incorporate new and evolving technologies into our regulation of OCS oil and gas activities. The regulations applicable to MODUs conducting exploratory drilling on the Arctic OCS reflect these efforts. The relief rig, SCCE, and other regulations require a coordinated and redundant system to provide for adequate safety in exploratory drilling operations under the uniquely challenging environmental and operational conditions on the Arctic OCS. BSEE has determined the finalized provisions in this rulemaking provide for the appropriate redundancy and sequencing of the responses, based on deployment time and varying equipment capabilities, and therefore provides the necessary level of safety and environmental protection to allow for exploratory drilling on the Arctic OCS.

One commenter further questioned BSEE's support for requiring a relief rig for exploratory drilling operations from a MODU or jack-up on the Arctic OCS, and requested identification of the administrative record. The commenter asserted that BSEE should allow for public comment on the administrative record when it is publicly identified.

Generally defined, an administrative record is a compilation of the body of information considered directly or indirectly by an agency decision-maker in arriving at a final decision. The administrative record is created from the decision record, which is an evolving resource through development of the proposed rule on to promulgation of the final rule. Public comments, including those submitted by the commenter, are part of the administrative record. As it does with all of its proposed rules, BSEE invited public comments on the NPRM and supporting documents and data to ensure that it considers a wide range of environmental, economic, and other issues related to the proposed rule. The commenter submitted this comment during the public comment period of the rulemaking process, and therefore prior to the final agency decision. The administrative record is complete when the Department issues the final rule, not before. In addition, administrative records are not subject to public review and comment requirements under applicable law. We note, however, the public may view the public rulemaking docket at any time. The docket, available at *www.regulations.gov*, contains all public comments, as well as additional documents and information relied upon in the finalization of these regulations. BOEM and BSEE carefully considered all comments on the proposed rule on the requirement for a relief rig—along with a host of other resources that make up the overall administrative record—and, as discussed previously, determined that the requirement for a relief rig is both necessary and appropriate for exploratory drilling operations on the Arctic OCS.

Several commenters oppose the 45-day maximum limit on the time necessary to complete relief well operations and request that BSEE allow for a performance-based requirement to determine the end of drilling season date on a case-by-case basis. Many of the commenters also state the 45-day limit unnecessarily shortens the drilling season on the Arctic OCS, and consequently lessens the value of existing leases.

BOEM and BSEE note the proposed 45-day maximum limit does not seek to impose a specific requirement. The 45-day threshold marks the maximum time allowed, but the requirement is performance-based and leaves the means of compliance up to the operator.

BOEM and BSEE will take a precautionary approach to evaluating proposals to complete relief well operations,[42] particularly those proposing a window of less than 45 days. This evaluation will be part of the review by BOEM in the EP process under § 550.220(c)(4) and BSEE in the APD process under § 250.470(e). BOEM and BSEE will apply a presumption that 45 days is the appropriate amount of time needed to ensure successful completion of relief well operations, including safe transit from the well site. Any proposal by an operator that seeks to demonstrate the ability to complete relief well operations in less than 45 days will be made public by BOEM's posting of the operator's EP once it is deemed submitted. The public will have an opportunity to review and comment on the EP, including the operator's plans for completing relief well operations in 45 days or less. If an operator seeks to make such a demonstration, BOEM and BSEE will undertake a rigorous, data-driven approach to ensure that sufficient time is allocated for the operator to complete relief well operations. Specifically, BOEM and BSEE will require that the length of the shoulder season encompass the amount of time that is needed to ensure successful relief well operations, taking full account of the cumulative risk of delay across the steps required for completion of relief well operations, including potential delays that may occur due to the following: Weather disruption, the presence of ice that cannot be handled by any available ice breakers and other ice management vessels, equipment or process malfunctions, uncertainties associated with the duration of time required to achieve successful relief well intervention, and any other variables related to relief well operations. Whether the deployment of ice breakers or other ice management vessels is included in the EP will also be evaluated. A reduction below 45 days will be granted only to the extent justified after applying this precautionary approach to assessing plans.

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[42] Operators may request approval to use alternative compliance measures that meet or exceed the level of safety and environmental protection in accordance with § 250.472. This evaluation would also apply to any approved alternative compliance measures.

One commenter expressed concern that current technology has not advanced to a point where oil can be effectively cleaned up when mixed with ice, or worse, trapped under the ice.

BSEE understands the commenter's concern, but notes the finalization of this rulemaking specifically limits operations to the open water season and requires early termination of operations when drilling below or working below the surface casing. The early termination is designed not only to allow the drilling of a relief well, but also to enable the use of oil spill response equipment prior to freeze-up. BSEE acknowledges, in certain situations, some cleanup of oil in ice could become necessary, and has required operators to develop oil intervention practices that will enhance the effectiveness of spill countermeasures when dealing with oil in broken ice conditions. Oil spill response techniques do exist for responding to oil spills in Arctic conditions. Research and development designed to improve oil spill response countermeasure technologies and procedures are continuous and ongoing, including efforts that are funded by both government and industry entities.

One commenter generally supported this rulemaking's emphasis on equipment redundancy to contain or control a WCD. The commenter recommended revising this section to encourage operators to demonstrate the success rate of capping operations and equipment, as well as to provide confidence levels of dealing with a number of discharge scenarios.

BSEE disagrees with the recommended revision. As discussed previously, the relief rig requirement is not the primary method of control or containment. The commenter's concern for encouraging redundancy is addressed in § 250.471, which requires Arctic OCS operators to have a capping stack stationed nearby for prompt deployment to an out-of-control well as an initial line of response. BSEE does not propose the relief rig as an alternative to the capping stack, but rather as a supplement to the capping stack, serving the distinct purpose of permanently killing and plugging the well. Regarding opportunities to demonstrate the success rates of capping operations and equipment, § 250.471(b) requires stump testing of capping stacks at specific intervals, and § 250.471(d) directs operators to conduct testing when directed by the BSEE Regional Supervisor. Accordingly, we agree there should be redundant capabilities covering a wide range of scenarios to be employed during an emergency situation, and the finalized provisions of this rulemaking adequately address this issue ensure.

Two commenters requested that, if the 45-day maximum timeframe is finalized, the WCD regulations at § 254.26(d)(l) should be revised to align with the maximum time allowed to drill a relief well, such that the operator must plan for a blowout lasting up to 45 days. Another commenter expressed general concern for how the WCD is calculated.

BSEE has determined the differing timeframes do not necessitate a revision at this time. The 45-day provision is the maximum timeframe allowed for an operator to move the relief rig to the site of the blowout and complete all necessary operations to kill and abandon the original well and abandon the relief well prior to seasonal ice encroachment. Existing regulations in § 254.26 provide a broad performance-based standard requiring plan holders to establish what a WCD would be, and then ensure that enough response and supporting resources are available to clean up such a discharge. Although § 254.26(d)(1) provides the WCD scenario must show how an operator will support operations for a blowout lasting 30 days, it does not preclude developing a scenario lasting longer than 30 days, nor does the hypothetical prospect of a spill lasting longer than 30 days necessitate revision of that regulatory timeline. Accordingly, NTL 2012–N06 *Guidance to Owners and Operators of Offshore Facilities Seaward of the Coast Line Concerning Regional Oil Spill Response Plans,* encourages operators to consider a variety of factors when developing a response strategy for each WCD, including planning to support response to a spill lasting longer than 30 days.[43]

One commenter suggests BSEE adopt a geographic prescriptive standard, requiring operators to maintain a relief rig within a certain distance of their drilling operation. The commenter asserted that the proposed performance-based requirements could still be maintained as a backstop in order to impose liability on any operator that fails to drill a relief well in a timely manner, even while compliant with the prescriptive standards.

BSEE disagrees. As discussed in the preamble to the NPRM, we did consider a prescriptive geographic standard, but based on both 2012 and 2015 operational experience and public comments to the proposed requirements of § 250.472, we determined to retain the 45 day maximum time allowance within a performance-based requirement to provide the operator flexibility to innovate and avoid unanticipated logistical consequences.

One commenter requested that BSEE mandate an additional 10-day buffer period before an operator's established end of season date to allow for unforeseen circumstances. The commenter asserted the additional time added to the end of season date will help mitigate the risk of relief well operations not being completed before the encroachment of winter sea ice and avoid the consequences of a spill continuing until the following open water season.

BSEE has determined it is not necessary to impose a mandatory additional 10 day buffer, because this rulemaking specifically limits operations to the open-water season. The requirement to be able to complete relief well operations prior to the expected encroachment of seasonal ice results in the end of drilling operations well in advance of winter sea ice encroachment and therefore provides an adequate buffer to accommodate the risks of a late season loss of well control. Further, a significant portion of the last 10 days of operations will be spent permanently or temporarily abandoning a well and most of the operations occurring at the end of the drilling season will be significantly safer than the drilling itself. Because the regulations already require operators to stop drilling below or working below the surface casing well before the encroaching ice season, BSEE does not believe a mandatory 10-day buffer period is necessary to further mitigate risk.

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[43] Available at *http://www.bsee.gov/Regulations-and-Guidance/Notices-to-Lessees-and-Operators.*

Two commenters request clarification of how an operator will calculate the expected onset of seasonal ice encroachment when determining the end of seasonal operations to meet the proposed requirements of § 250.472. The commenters express concern that the calculation does not take into account periodic ice incursions during the open water season, and how potential ice management activities, which could include rig movement, interact with this requirement.

BSEE clarifies that the operator will calculate the freeze-up date based on historical data and will update it daily, in conjunction with the daily ice reports, as the season nears its end. Periodic ice incursions occur mostly during the early part of the open water season as the ice breaks off and floats away. Section 250.472 relates to the projected return of seasonal sea ice to the drilling site at the end of the open water season. However, an operator's ice management plan is always in effect with the included ice monitoring provisions.

One commenter asserted that the language of § 250.472(b) prohibiting "drilling below or working below the surface casing" during the relief well buffer period conflicts with the proposed provisions at § 550.220(c)(6), requiring "[t]he termination of drilling operations into zones capable of flowing liquid hydrocarbons to the surface." The commenter asserted that, taken literally, an operator could not even conduct operations that are required by regulations during this relief well buffer period. The commenter suggests that, as drafted, the BOEM provision of part 550 references § 250.472 and that the more restrictive BSEE language would prevail if the two sections were reconciled. The commenter requested the conflict between the two provisions be addressed in a re-proposed rule by retaining the language under proposed § 550.220(c)(6), and removing the applicable language of § 250.472(b).

We agree with the commenter in part. The intent of § 550.220(c)(6)(ii) is to obtain the information that is known at the time of EP submission regarding the operator's plans for compliance with the requirements of § 250.472(b). Therefore, as a technical correction, we removed the text of "into zones capable of flowing liquid hydrocarbons" from § 550.220(c)(6)(ii) in this final rule. There is no need to re-propose this provision because the intent of § 550.220(c)(6)(ii) was stated as requiring the operator to include in the EP information "consistent with the relief rig planning requirements under § 250.472" and this revision does not change the intent of § 550.220(c)(6)(ii) as proposed. We disagree with the commenter's second suggestion that the proposed language of § 550.220(c)(6) should be retained, instead of the finalized language of § 250.472(b), "drilling below or working below the surface casing." Operators may drill or work down to the surface casing at any time. However, the risk of a blowout is increased while working or drilling below that casing, including before drilling into areas expected to be capable of flowing liquid hydrocarbons (such as by way of example, shallow gas pockets). Therefore, the finalized language "below the surface casing" ensures that an operator stops at that last casing point, or pulls back and temporarily plugs at that casing point, to meet the requirements of § 250.472(b) and have appropriate capabilities to complete the relief well sufficiently in advance of seasonal ice encroachment.

One commenter suggested the end of seasonal operation dates should not be determined by the operator.

BSEE disagrees. The anticipated end of season date is determined by the operator because they have the primary responsibility to conduct operations in a safe and environmentally responsible manner. They also have the best access to the relevant information related to their equipment and capabilities to operate within certain conditions and timelines (*e.g.,* how long it will take to complete a relief well based on their planned relief rig equipment and staging). Additionally, the operator is in the best position to manage adaptively the extent of operations in the Arctic in light of rapidly changing late-season conditions and in recognition of the extremely short drilling season. BOEM and BSEE provide the regulatory oversight of exploratory drilling operations, however, and any determination of projected end of season dates made by the operator must be reviewed by BOEM and BSEE under the provisions of the EP (§ 550.220(c)(6)) and the APD (§ 250.470(e)). BOEM ultimately approves the end of season date and would need to approve any changes made to the date established in the EP.

One commenter suggests BSEE require relief rigs be in the Arctic OCS area where drilling is underway, to allow the rig to be in place and operating within one week of a blowout occurring.

BSEE agrees with the commenter's concern for a timely response in the event of a blowout occurring. However, BSEE determined the best method of protection is not to prescriptively require an operator to stage a relief rig within a specific geographic area. While BSEE considered imposing such a requirement, we ultimately determined that the performance-based approach of establishing a 45-day maximum, but otherwise permitting the operator to determine its approach to relief rig staging, was preferable. This approach allows the operator flexibility in the management of its rigs while still ensuring that basic safety and environmental protection standards are met. Additionally, the response capabilities finalized in § 250.471 for SCCE will be activated and deployed at the same time that the relief rig is moving into location, mooring up and getting ready to drill, with the initial response required within 24 hours. The relief rig and SCCE requirements are not mutually exclusive operations and can proceed concurrently.

One commenter expressed concern that mutual-aid agreements or cooperatives formed to share relief rigs may inhibit the effectiveness of response. The commenter recommended the final rule set limits on continued drilling of any well relying on a particular relief rig if a blowout occurs and that rig is dedicated to blowout response.

BSEE agrees with the commenter and believes this issue is addressed in the performance standard finalized at § 250.472(b), and incorporated into the operator's approved EP (§ 550.220(c)(4)) and APD (§ 250.470(e)). An operator is required to have access to a relief rig, different from the primary rig, that is able to move onsite to drill a relief well, kill and abandon the original well, and abandon the relief well prior to seasonal ice encroachment at the drill site, but no later than 45 days from a loss of well control. The commenter is concerned with a circumstance in which a single relief rig is relied upon to provide the necessary capabilities for multiple operations (pursuant to a mutual aid or cooperative agreement), and is called into service by a well control event at one of the well sites. Under such circumstances, any other continued drilling operations that rely on the availability of that relief rig must stop, as the relief rig would no longer be available to respond within the parameters required by the regulation and the operator's approved EP and APD.

Two commenters recommend the final rule include a provision requiring operators to submit a Relief Well Drilling Plan as part of the EP application in § 550.220. The commenters further assert that such plans are critical in any case where a mutual aid agreement is used to share a relief well drilling rig, to ensure that drilling operators agree to provide relief well personnel that are trained, qualified, and prepared to provide the services they offer to share.

BSEE agrees with the commenters' concerns that useful and important information about the relief rig should be required in the EP, and believes that the final regulations are sufficiently protective as finalized, without the need for an additional plan as suggested by the commenters. Although not specifically entitled a "Relief Well Drilling Plan", § 550.220(c)(4) requires an operator to include with the EP a general description of how they will comply with the relief rig requirements of this section, including a description of the relief well rig, the anticipated staging area of the relief well rig, an estimate of the time it would take for the relief well rig to arrive at the site of a loss of well control, how the operator would drill a relief well if necessary, and the approximate timeframe to complete relief well operations. The EP process provides an opportunity for the public to review and comment on any submissions related to relief well operations, including the anticipated length of time to drill a relief well and complete relief well operations. Additionally, § 250.470(e) requires that the APD include a detailed description of how an operator will comply with the relief rig requirements of § 250.472. This information is required at both the EP and the APD stages because we expect an operator to have more detailed information as they move closer in time toward the exploratory drilling operations. The planning and descriptions required by these provisions ensure adequate attention to these issues.

One commenter suggests that, if a rig is strictly dedicated as a relief well rig, it still needs to be subject to the same audit, inspection, and testing requirements as an operating rig before it is approved as a stand-by rig to allow for the rig to be verified and ready for immediate use in an emergency. The commenter also recommended all records be retained for a consistent period and electronically submitted to BSEE, unless BSEE can explain the reason for recommending a different record retention schedule.

BSEE acknowledges the commenter's concern and notes that any dedicated standby rig contracted to an operator is subject to the same qualification, inspection and testing requirements as a rig with drilling activities underway. Section 250.472(a) expressly states that "[y]our relief rig must comply with all other requirements of this part pertaining to drill rig characteristics and capabilities, and it must be able to drill a relief well under anticipated Arctic OCS conditions." Similarly, a dedicated standby rig is subject to the enhanced SEMS auditing requirements (*see* § 250.1920(f)) when supporting operations on the Arctic OCS. This means that the existence and effectiveness of the SEMS must also be tested on the standby rig, in addition to the active drilling rig or rigs, during the 30 day period after drilling activities commence in that field of operations.

BSEE disagrees with the comment regarding record retention. The record maintenance requirements in the proposed rule are intended to mirror, to the extent possible given the long lead times and down periods in Arctic exploratory drilling, current regulations. *See* §§ 250.426, 250.434, 250.450 and 250.467. BSEE also disagrees that electronic submission should be required and at this time we determined electronic submittal of records should remain optional.

One commenter asserted that the use of an SID should be considered only in the case of a jack-up MODU, specifically to be employed to allow the jack-up to be moved off location in the event of unmanageable hazardous ice encroachment. The commenter explains that, for floating MODUs, the SID would not add benefit, as the subsea BOP is already deployed at the seabed and the SID would require a much deeper mud line cellar, which raises additional risks for the mud line cellar construction and soil stability.

BSEE agrees with the commenter. The final rule does not require an SID, although it may be requested as alternate technology or procedure for use with a jack-up under appropriate circumstances, pursuant to § 250.141. The BOP is already subsea with a floating drilling unit, so an SID would be only marginally effective or redundant.

One commenter requested that BSEE clarify why the decision to commence relief well drilling may be made by the Regional Supervisor. The commenter asserted that such decisions should be made by the operator because it will have the best understanding of the real-time situation and the most prudent sequence of steps. The commenter suggests that, if BSEE seeks to direct active drilling operations, further clarification is required on BSEE's responsibility, accountability, and liability in the event of any incidents that occur as a direct result of those actions.

BSEE anticipates that decision-making regarding appropriate sequencing and execution of well control activities in the event of the operator's loss of well control will involve cooperation between BSEE and the operator, in light of the operator's familiarity with its circumstances, conditions, and capabilities. BSEE is not seeking to direct active drilling operations and clarifies that its role is to enforce existing regulations to protect rig personnel, the environment, and the natural resources of the OCS, which may include ordering an operator to drill a relief well. In the event of a loss of well control, the Regional Supervisor may direct the operator to commence drilling a relief well; however, it remains the operator's responsibility to manage active drilling operations, in accordance with the requirements of the regulations to respond to a loss of well control. Questions concerning liability are beyond the scope of this rulemaking. BSEE is authorized to prescribe rules and regulations that are necessary to carry out the provisions of OCSLA. (43 U.S.C. 1334(a)). Section 250.472 requires the operator to have access to a relief rig that is different from the primary rig, and that will arrive on site, drill a relief well, kill and abandon the original well, and abandon the relief well prior to expected seasonal ice encroachment at the drill site, but no later than 45 days after the loss of well control. This requirement does not specify how any relief well will be drilled. Drilling a relief well (in accordance with an approved APD and any conditions included therein) will continue to be the operator's responsibility.

One commenter questioned the authority of the Regional Supervisor to direct an operator to commence relief well operations, which is an oil spill source control activity and therefore within the jurisdictional authority of the FOSC, not the Regional Supervisor.

BSEE disagrees. The drilling of a relief well is an emergency well control measure that is conducted under regulations implementing OCSLA. As such, the BSEE Regional Supervisor has the authority to require the operator to begin relief rig operations as part of their responsibilities under the OCSLA.

One commenter requested clarification on why BOEM and BSEE are proposing additional regulations for relief rigs if they already have the existing authority to require relief rigs for exploratory drilling on the Arctic OCS. The commenter cites the NPRM preamble: "BOEM and BSEE anticipate that we would exercise our existing authorities to require a relief rig for any future exploratory drilling on the Arctic OCS" (see 80 FR 9948).

BOEM and BSEE have broad authority under existing regulations to impose reasonable conditions on exploration plans and drilling permits. We included the express requirements for a relief rig in § 250.472 because this provision clearly articulates that BOEM and BSEE will require access to a relief rig during all future exploration activities on the Arctic OCS, unless an operator is able to obtain approval for alternative compliance measures under § 250.141 and this final rule at § 250.472(c). This explicit requirement should allow operators to plan for all of the types of vessels, equipment, and personnel that will be required to conduct exploratory drilling operations on the Arctic OCS, and on what terms.

One commenter recommended § 250.472(a) be revised to insert the word "safely," whereby an operator would be required "to safely drill a relief well under anticipated Arctic OCS conditions."

BSEE agrees with the commenter's premise, but notes the requirement for safe operations is the primary goal of all our regulations, and as such this obligation is captured throughout the regulations. For example, § 250.107, *What must I do to protect health, safety, property, and the environment?*, requires that all OCS operations be conducted in a safe manner and all equipment be maintained in a safe condition. Accordingly, the revision proposed by the commenter is already implicit in the regulatory requirement and an obligation of the operator, and is therefore unnecessary.

One commenter suggests that, if an operator drills a well to total depth during the drilling season prior to the time set aside for a relief well, then that time could be effectively utilized for logging and well evaluation.

BSEE disagrees. The final regulations at § 250.472 prohibit working (*e.g.*, logging and well evaluation) or drilling below the surface casing when seasonal ice encroachment is expected before the relief rig could complete relief well operations. BSEE has determined that the risk associated with drilling below or working without the ability of the relief rig to arrive on site, drill a relief well, kill and abandon the original well, and abandon the relief well prior to expected seasonal ice encroachment at the drill site, is too great to allow for such operations. The operator could, alternatively, use this period to perform operations above the surface casing, such as drilling mudline cellars or top holes and setting surface casing in preparation for future operations.

What must I do to protect health, safety, property, and the environment while operating on the Arctic OCS? (§ 250.473)

BSEE proposed to add a new § 250.473 that would require performance-based measures in addition to those listed in § 250.107 to protect health, safety, property, and the environment during exploratory drilling operations on the Arctic OCS. Several comments were received on this section. BSEE has reviewed the comments and determined to finalize § 250.473 as proposed.

The majority of commenters were generally supportive of the requirements of § 250.473, and consider the finalized requirements good business practice and appropriate environmental stewardship.

One commenter suggests that the performance-based requirements could be supported by established and well known standards, such as International Electrotechnical Commission (IEC) 61508 and 61511.

BSEE has determined that no revision is needed here because these issues are addressed by our existing SEMS requirements at Part 250 subpart S, which are performance-based. The SEMS requirements are primarily based on API RP 75, which was specifically developed for the offshore oil and gas industry. The operator's SEMS must meet or exceed the standard of safety and environmental protection of API RP 75. The goal of the operator's SEMS is to promote safety and environmental protection by ensuring all personnel aboard a facility are complying with the policies and procedures identified in the operator's SEMS.

One commenter recommended adding a requirement that the operator train personnel for the environmental conditions present in the Arctic. The commenter asserted that an understanding of wind chill, frostbite, and proper safety procedures around ice-covered equipment is as necessary as having arctic-grade hydraulic fluid in the lines.

BSEE agrees that a well-trained crew plays an important role in achieving safe and professional drilling operations. We believe that the training requirements in our current regulations provide the basis for appropriate training for crews working in Arctic conditions. Section 250.1501, *What is the goal of my training program?*, requires training to ensure that employees and contractors can perform the duties associated with their jobs, and § 250.1915, *What training criteria must be in my SEMS program?*, requires implementation of a training program developed in accordance with employee duties and responsibilities for use in the SEMS programs. BSEE also believes that the requirement of § 250.473 to address human factors associated with Arctic OCS conditions can and should include training designed to address such factors. These regulatory provisions seek to ensure that operators provide for adequate training of workers specific to their positions and the conditions under which they will perform.

What are the auditing requirements for my SEMS program? (§ 250.1920)

BSEE proposed to revise existing § 250.1920 to increase the audit frequency and facility coverage for intermittent Arctic OCS exploratory drilling operations. While operators are generally required to conduct their SEMS audit every 3 years after their initial audit, BSEE proposed to require a SEMS audit of Arctic OCS exploratory drilling operations and all related infrastructure each year in which drilling is conducted, because of the particularly challenging conditions and high-risk nature of those activities. This Arctic OCS audit would require operators to ensure that all safety systems are in place and functional prior to commencing or resuming activities for a new drilling season, as well as to conduct the offshore portion of the audit while drilling is under way. An operator conducting Arctic OCS exploratory drilling operations may not combine its Arctic OCS facility audit(s) with audits of its non-Arctic OCS facilities to satisfy the facility sampling requirements incorporated into Subpart S.

Many comments were received on this section. BSEE has reviewed the comments, and made various technical edits in response to the comments. The remaining substantive provisions of § 250.1920 are finalized as proposed, as discussed herein.

Several commenters generally support this provision. Three of these commenters supported the requirement for annual SEMS audits with suggested revisions. One commenter recommended that the new provision clearly state that BSEE will ensure that any identified non-compliance in the onshore audit is remedied prior to the start of drilling, and that the operator will be required to immediately notify BSEE of any non-compliance identified in the offshore audit so that BSEE can make an immediate and informed decision on whether to allow continued offshore operations. Another of the commenters suggested that the time frame for submittal of the audit report be expedited to 15 days, and that the Corrective Action Plan (CAP) include a plan to remedy all deficiencies or nonconformities no later than 30 days after the offshore portion of the audit. Similarly, a commenter suggested a review strategy be put in place allowing for evaluation of the management strategies and regulations instituted under this final rule during the off season to mandate that recent experience as well as advances in technology and systems design always be used to improve the effectiveness of the operator's SEMS.

BSEE agrees that an annual SEMS audit is a prudent requirement for Arctic OCS exploratory drilling. BSEE also recognizes that the audit requirement implicates more than simply having a management system in place. An audit of a good management system will identify ways that the management system is meeting its objective of hazard identification and risk management. The same audit is just as likely to identify ways that the management system is functioning but can do a better job.

BSEE is not changing the schedule for submittal of audit findings in this final rule. Developing a comprehensive audit report and effective CAP within 30 days of an audit will require considerable discipline and focus. BSEE believes that a shorter time frame would compromise the quality of both submittals. In addition, the time frame to complete any proposed corrective actions should not be specified in the rule, as the appropriate time frame for correction is largely dependent upon the nature of the nonconformity. This will continue to be a subject for discussion between the operator and BSEE as currently allowed by the regulation. With respect to BSEE's ability to ensure timely compliance, finalized § 250.1920(g) provides that, "if BSEE determines that the CAP or progress toward implementing the CAP is not satisfactory, BSEE may order you to shut down all or part of your operations."

BSEE also does not believe that it is necessary to specify that off-season evaluation of the SEMS needs to be performed. Operators have discretion within their own management systems on how to identify and prioritize continual improvement opportunities, and our specifying how to do this could be counterproductive. Finally, BSEE believes that the schedule for submittal of the audit findings will allow BSEE to intervene quickly if a management system is not in place, as when an operator's continual improvement efforts appear inadequate.

Several commenters request that BSEE remove the annual auditing requirements of § 250.1920(b)(5). The commenters assert that such a frequency of auditing is not needed, has not been justified, and will not have an impact on safety or compliance because an operator's SEMS program does not typically change on an annual basis. In addition, commenters state that existing BSEE regulations require an audit of the SEMS program on a three-year cycle, which has worked effectively for operations in the Gulf of Mexico and they assert should be more than adequate for operations in the Arctic OCS. One commenter suggests that an annual audit frequency may actually reduce health, safety, security, and environmental performance, and requiring an annual SEMS audit on existing operations will result in added time delay to conduct audits without any demonstrated improvement to safety.

BSEE disagrees with these comments. Operators engaging in exploratory drilling on the Arctic OCS will be managing risks that are novel and untested compared to those encountered in the Gulf of Mexico. Arctic operations are seasonal and will include mobilization and demobilization activities each year within short time windows. Changes to an operator's management system (both in design and in the personnel who will be relied upon to implement it) are likely to be required as new hazards are recognized and managed, and as contractors rotate in and out of the field. Accordingly, an operator's Arctic SEMS program will likely change over the course of a year. Annual auditing is a way to determine if the organization is continually improving its management system as it gains experience with the new risks and the changing environmental and organizational conditions. If an operator finds that audit results do not contribute to improved approaches to safety and environmental protection, then it is possible that the audit approach needs to be changed rather than resorting to a less frequent audit.

Several commenters suggest additions to the content of SEMS audits for exploratory drilling operations on the Arctic OCS. One of the commenters suggests the SEMS audit should be extended to address the status of key barriers and assess ice management, as well as evaluate the Arctic operator's safety culture. Another of the commenters asked that the SEMS audit include a focus on contractor management and oversight. One of the commenters suggests the proposed regulatory text be revised to include a reference to the onshore portion of the audit incorporating a physical audit of all major equipment proposed in the EP and APD (including at a minimum the drilling rig, SCCE, relief rig, and support vessels) to verify this equipment is ready and capable. The commenter also recommended the revision address the offshore portion of the audit, including requiring a physical audit of all equipment used to execute the EP and APD in the Arctic OCS while drilling is underway. The same commenter asked that the SEMS audit require an audit of 100 percent of the equipment instead of 100 percent of the facilities.

BSEE agrees that those who audit Arctic operations need to examine contractor management elements of their SEMS, as well as review the barrier analysis and barrier readiness aspects, including ice management, weather and ice forecasting, ice and marine mammal monitoring, and response to ice encroachment. BSEE notes, under existing §§ 250.1914 and 250.1924, BSEE has broad authority to require operators on the Arctic OCS to provide BSEE with appropriate contractor information, such as the names of contractors and the specific scope of their duties and timelines for performance in support of an operator's drilling activities. For example, if an operator planned to use a contractor for waste disposal, cementing, or logging, BSEE would expect the operator to inform BSEE of this intent, along with any other operations contracted out, and the names of those contractors. BSEE intends to work with the Accreditation Bodies it names pursuant to § 250.1922 to define and hold auditors accountable for evaluating the management system's effectiveness in addressing these risk areas.

BSEE disagrees that the scope of the audit should include inspection of equipment. The purpose of a management system audit is to determine if the processes and systems adopted by an operator to manage risk are in place and effective, not to test and inspect the functionality of every piece of equipment within the management system. BSEE conducts thorough facility and equipment inspections through its own inspection program. *See, e.g.*, §§ 250.130 through 250.133.

One commenter expressed concern that there would be a shortage of qualified independent third party auditors.

BSEE disagrees that a possible shortage of qualified auditors should be a basis for challenging the annual SEMS audit requirement on the Arctic OCS. The commenter did not provide evidence that there is or will be a shortage of qualified auditors, or that the marketplace would not be able to respond appropriately.

One commenter requested further clarification on the associated responsibility, accountability and liability BSEE will assume in the event of any incidents occurring as a direct result of what the commenter describes as BSEE seeking to direct active drilling operations. The commenter urges BSEE to leave key operational decision-making in the hands of the operators and focus the regulations on ensuring that drilling plans and operations are risk based and fit for purpose for every proposed location.

BSEE does not direct active drilling operations, nor intend to do so in the future through this rule. Operators responsible for directing the drilling operations are required to do so safely and in accordance with the regulations. BSEE has the authority to require compliance with the regulations, but in doing so does not assume any accountability or liability for incidents arising from the regulated operations. It is the operator's responsibility to conduct its activities both safely and in accordance with its regulatory obligations. Operators must also have access to all of the information needed to make their own decisions on how to mitigate safety and environmental impacts from the hazards they will face. One purpose of the SEMS audit is for the operator to gain a third-party assessment of their own ability to effectively manage risks. BSEE does not use the results of the SEMS audit to tell operators how to manage the risks, but instead evaluates those results as one part of its oversight responsibilities to ensure that the operators have systems in place that are effectively risk-focused and fit for purpose.

One commenter asked that BSEE consider a Safety Case approach to ensure functionality of Health Safety and Environment and Quality management systems, and compliance of rigs and contractors, similar to the approach established on the Norwegian Continental Shelf and in the United Kingdom.

BSEE declines to adopt this suggestion. BSEE has adopted a hybrid approach to safety and environmental regulation on the OCS. BSEE and BOEM have determined that Arctic exploratory drilling operations should be guided by a number of specific requirements to ensure protection of workers and the environment. We note that the final rule clearly allows for specific requirements to be met by employing new and emergent technology, when appropriate. Given the significant risks associated with Arctic drilling operations, complete reliance on a safety case approach, in the view of BSEE and BOEM, does not offer enough regulatory oversight.

Oil Spill Response

Part 254—Oil-Spill Response Requirements for Facilities Located Seaward of the Coast Line

Definitions. (§ 254.6)

BSEE proposed to insert in the proper alphabetical order new definitions for *Adverse weather conditions, Arctic OCS* and *Ice intervention practices* to existing § 254.6. One comment was received to the definition for *Adverse weather conditions* and is discussed below. No other comments were received on the proposed addition of the definitions and the provisions are finalized as proposed.

One commenter claimed that the revised definition for Adverse Weather Conditions disregards the safety of responders and would set in place operating limits that would delay the cessation of response activities until equipment is destroyed or responders are fatally injured. The commenter suggests that BSEE replace the definition with language adopted from the State of Alaska's regulations, which require a plan holder to define realistic maximum response operating limitations, as per 18 AAC 75.425(e)(3)(D).

BSEE disagrees with this comment. The final rule adds the terms "extreme cold, freezing spray, snow, and extended periods of low light" to the list of conditions in the existing definition that may degrade the operating environment on the Arctic OCS. Adopting these terms in the final rule provides a more thorough description of the types of challenges a plan holder's response resources must be prepared to address in responding to a discharge on the Arctic OCS, but in no way establishes operational limits, and certainly does not create any expectation that responders will continue to operate in life threatening conditions. Operating conditions must be continuously evaluated and monitored during a response to ensure effective operations, but only when it is safe for responders to do so. The revised definition continues to state that Adverse Weather does not include situations where it would be dangerous to continue responding. The State of Alaska's cited regulations require the plan holder to define the maximum operating limitations for a mechanical recovery-based response, and to identify mitigating measures that may be instituted when those parameters are exceeded. This State requirement in 18 AAC 75.425(e)(3)(D) has a very different focus and intent and is not appropriate language for use in revising the definition of Adverse Weather Conditions for purposes of implementing the OPA.

OSRPs for Facilities Located in Alaska State Waters Seaward of the Coast Line in the Chukchi and Beaufort Seas. (§ 254.55)

BSEE proposed to add a new § 254.55 requiring the OSRP for any facility conducting exploratory drilling from a MODU in Alaska State waters seaward of the coast line within the Beaufort or Chukchi Seas to address the additional requirements set forth in the new subpart E, as finalized in this rulemaking. BSEE has authority under the CWA over oil spill response plans related to operations seaward of the coastline, including on state submerged lands. 33 U.S.C. 1321(j)(5); E.O. 12777; 30 CFR part 254, subpart D. Some requirements in subpart E address planning and exercises related to the use of source control and subsea containment equipment such as capping stacks or containment domes. Operators are required to have access to and use this equipment when conducting exploratory drilling from a MODU on the Arctic OCS, pursuant to finalized regulations in part 250, but those conducting similar activities in State waters are not currently subject to the same requirements. The State of Alaska, however, has State requirements for source control. As such, a response plan covering operations in State waters of the Beaufort or Chukchi Seas must address how the source control procedures selected to comply with State law would be integrated into the planning, training, and exercise requirements of proposed §§ 254.70(a) and 254.90(c).

Several comments were received on this section. BSEE has reviewed the comments and determined to finalize § 254.55 as proposed for the reasons stated herein.

One commenter requested that BSEE closely coordinate its OSRP requirements with the State of Alaska's requirements.

BSEE agrees, and for offshore facilities in State waters seaward of the coast line, BSEE will consult with the State to coordinate planning processes where possible. We note this rulemaking does not alter in any way the existing authorities or jurisdiction of BSEE or the State of Alaska. In addition, we note that, pursuant to existing § 254.53, operators in State waters may still rely upon OSRPs developed in accordance with the laws or regulations of Alaska, with certain modifications. Additionally, BSEE has a separate regulatory study underway that is evaluating the use of more specific deployment and response capability standards for each OCS region where oil and gas exploration and production is occurring. BSEE will review the State of Alaska's standards for facilities in State waters as part of this study, and will harmonize any future standards when it deems it is appropriate.

One commenter stated that the term "source control" is different than the term used in State requirements, which is "contain and control", and that using different terms will be problematic.

BSEE's position is this rulemaking addresses Federal requirements for offshore facilities in State waters seaward of the coast line, and does not impact state requirements. The State and Federal terms, while slightly different, are effectively similar in nature, and should not create any confusion for plan holders with respect to complying with either State or Federal regulations. While it is beneficial to use harmonized terms whenever possible between State and Federal regulations, it is just as important that Federal regulations use terminology that is consistent across various Federal rules and agencies. The term "source control" is defined in the National Contingency Plan as the construction, installation and startup of actions necessary to prevent the continued release of hazardous substances or pollutants or contaminants into the environment.[44] Source control is a consistently used term in other response-oriented doctrinal publications, such as the National Preparedness for Response Exercise Program (PREP) Guidelines and the USCG Incident Management Handbook.

Subpart E—Oil-Spill Response Requirements for Facilities Located on the Arctic OCS

Purpose. (§ 254.65)

A new § 254.65 was proposed to state the purpose for subpart E, described as establishing additional requirements for preparing OSRPs and maintaining preparedness for facilities conducting exploratory drilling operations from a MODU on the Arctic OCS. No comments were received on the proposed addition of this section and, with exception of one minor technical edit, the section is finalized as proposed.

What are the additional requirements for facilities conducting exploratory drilling from a MODU on the Arctic OCS? (§ 254.70)

BSEE proposed adding § 254.70 addressing general oil spill response planning requirements for operators using MODUs to conduct exploratory drilling on the Arctic OCS. These requirements include incorporating the support mechanisms for capping stacks, cap and flow systems, containment domes, and other similar subsea and surface devices and equipment and vessels, required by finalized § 250.471, into oil spill response incident action planning. They would also require operators to address the influence of adverse weather conditions on responders' health and safety during spill response activities. Finally, they would require operators, prior to resuming seasonal exploratory drilling activities, to review their OSRPs, and modify as necessary, to address changes to the location or status of response resources or the arrangements for supporting logistical infrastructure arising from extended periods of time without drilling.

Several comments were received on this section. BSEE has reviewed the comments and with the exception of one technical edit, the provisions of § 254.70 are finalized as proposed for the reasons discussed herein.

Many commenters recommend that BSEE should include an opportunity for public review and comment for OSRPs that address operations on the Arctic OCS.

BSEE disagrees. The National Response System that was set up under the CWA and the OPA establishes a system of plans, including a National Contingency Plan, regional contingency plans, area contingency plans, and facility and vessel response plans. National, regional, and area level plans all set policy on the use of oil spill countermeasures and all relevant strategies, and identify how sensitive resources must be protected. Regulatory agencies promulgate regulatory requirements for industry OSRPs, consistent with these higher-level plans requiring industry plan holders to have access to the requisite amounts and types of response capabilities. Agency review and approval of these plans is limited to ensuring the plans are consistent with national, regional, and area level guidance and ensuring the plans meet the pre-established regulatory requirements for capabilities and preparedness arrangements. Public comment and review is not necessary for the Agency to complete its review of the OSRP for compliance with the regulations, nor is there a meaningful role for the public where the pre-established standards of review leave little to no room for discretion. Under this existing paradigm, none of the industry response plans regulated by the Pipeline and Hazardous Materials Safety Administration (PHMSA), EPA, USCG or BSEE are subject to a public review and comment process. BSEE believes the most appropriate opportunities for public participation and comment on the relevant response issues are during the public comment periods associated with the oil and gas lease sales and EPs, public comment periods during the rulemaking process for establishing industry response plan regulatory requirements, and through interaction with the Area Committees, who develop the local Oil Spill Area Contingency Plans that provide guidance on the use of spill response countermeasures as well as protection strategies for specific sensitive habitats and species. In the case of the Arctic OCS, BSEE encourages interested parties to engage with the Alaska Regional Response Team, whose members include: The USCG; NOAA; Federal Emergency Management Agency; Federal Aviation Administration; General Services Administration; State of Alaska Department of Environmental Conservation; EPA; and Departments of Agriculture, Defense, Energy, State, Health and Human Services, Interior, Justice, and Labor, as well as the Northwest Alaska and North Slope SubArea Committees.

One commenter suggests that BSEE should develop the OSRP requirements using a risk-based environmental assessment process and design the response capabilities to address the specific risks of a spill from the offshore facility.

BSEE agrees with the commenter's concern, but notes the baseline requirements for an OSRP within § 254.26 already contain many provisions that are founded upon risk assessment processes. For example, plan holders must use oil spill trajectories from their offshore facility to assess any spill risks to resources and habitats, and design response capabilities appropriately. While this rulemaking adds additional detail that is necessary to ensure the oil spill preparedness measures are adequately designed for operating in the Arctic environment, it does not impose a new system of risk assessment processes for developing OSRPs upon plan holders that is outside of what currently exists in Part 254 or was proposed in the NPRM. Plan holders are free to adopt risk-based methods in developing their OSRP response strategies, as long as those strategies are in compliance with the regulatory requirements.

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[44] 40 CFR 300.5; *See generally* 40 CFR part 300, National Oil and Hazardous Substances Pollution Contingency Plan.

One commenter asserted that the type and number of resources that should be maintained in an area should reflect the most probable spill events that might occur.

BSEE disagrees. The OPA and BSEE's OSRP regulations require industry to plan for their WCD to the maximum extent practicable as a planning standard, and not for the size of their most probable spill, which would be considerably smaller. While response resources are strategically staged throughout the coastal zone near OCS regions where drilling occurs, BSEE acknowledges that in some cases equipment will be cascaded in from more distant areas in order to respond to a WCD, especially in the Arctic OCS.

One commenter suggests the regulations should allow for all types of response mechanisms to be in place, including the use of dispersants and in situ burning.

BSEE agrees industry OSRPs should include provisions for all of the oil spill response capabilities that are allowed for and consistent with the guidance contained within the relevant Regional and Area Contingency Plans (RCPs/ACPs). In the Arctic OCS, the guidance regarding, and strategies for, the use of dispersants and in situ burning is contained within the Unified Alaska Plan and the North Slope SubArea Contingency Plans. BSEE's OSRP regulations currently allow for the listing of both dispersants and in situ burning capabilities within industry OSRPs. A regulatory study entitled, "Oil Spill Response Equipment Capabilities Analysis," is currently underway that is considering additional requirements for ensuring the availability of these spill countermeasures in all areas of the OCS where drilling is occurring or may occur, including the Arctic.

One commenter suggested that the duration of a WCD required by § 254.26(a) for drilling operations should be extended beyond 30 days to whichever is greater, a period of 45 days or the time it would take to drill a relief well. The commenter further recommended that the method to calculate the WCD daily flow rate should be amended and based on offset well data; if no offset well is available, the commenter recommended that minimum default values of 61,000 barrels of oil per day for wells in the Chukchi Sea, and 25,000 barrels of oil per day for wells in the Beaufort Sea, should be adopted.

BSEE agrees in part. Based on the lessons learned from the *Deepwater Horizon* response, BSEE released National Notice to Lessees and Operators of Federal Oil and Gas Leases and Pipeline Right-of-Way Holders (NTL) No. 2012–N06, "Guidance to Owners and Operators of Offshore Facilities Seaward of the Coast Line Concerning Regional Oil Spill Response Plans." NTL No. 2012–N06 encourages operators to identify sources for supplies and materials that can support a response to an uncontrolled spill lasting longer than 30 days. However, BSEE has determined that further study is required before revising 30 CFR part 254 to extend the duration of a WCD. BSEE has a regulatory study entitled, "Oil Spill Response Equipment Capabilities Analysis," underway to consider various options for amending the period of time for which an operator must plan to support response operations. With regard to daily flow rates, § 254.47 states that an operator must calculate the size of their WCD scenario as the daily volume possible from an uncontrolled blowout, but does not go into detail about how that flow rate calculation must be made. Rather, the daily flow rate information referenced in the OSRP is based upon data generated earlier in the permitting process for the associated EP as required by BOEM in § 550.213(g) and NTL No. 2015–N01, "Information Requirements for Exploration Plans, Development and Production Plans, and Development Operations Coordination Documents on the OCS for Worst Case Discharge and Blowout Scenarios". BSEE does not believe that it would be appropriate to institute minimum default values in lieu of the prescribed methodology.

Two commenters indicated the regulations should provide more detailed guidance on what oil spill planning and response capabilities should be required to adequately respond to an oil spill in the Arctic. One of the commenters provided detailed recommendations for what those requirements and capabilities should entail.

The existing regulations in § 254.26 provide a broad performance-based planning standard for establishing a plan holder's WCD identifying the anticipated impacts, and ensuring the availability of enough response and supporting resources to protect or clean up the environment from such a discharge. BSEE is reviewing the possibility of providing more detailed requirements for response capabilities in a future rulemaking, and will consider the recommendations provided in these comments as an input for that process. Until that time, it is the plan holder's responsibility to develop response capabilities that will satisfactorily meet the existing planning standard.

One commenter argued that most drilling in the Arctic is in extremely shallow water from gravel islands, and that use of SCCE equipment in those cases is not practicable.

BSEE agrees. The SCCE requirements of this rulemaking only apply to MODUs conducting exploration drilling, and therefore would not apply to shallow water drilling from gravel islands.

Two commenters assert that adding SCCE information to the OSRP would confuse responders and unnecessarily increase the size of the OSRP. The commenters suggest that SCCE information should be kept in a separate planning document, and one of the commenters specifically recommended that OSRPs reference well containment plans instead.

BSEE agrees in part. SCCE are critical capabilities required for certain plan holders in order for them to meet their requirements in existing § 254.26(d) for responding to their WCD. Further, SCCE will be deployed and utilized alongside spill response equipment, necessitating coordinated planning for an integrated approach to a loss of well control. As such, OSRPs must include certain essential information about SCCE capabilities. BSEE agrees that most SCCE information can be maintained in separate well control-oriented planning documents (as required by § 550.220(c)(3) (EPs) and § 250.470(f) (APDs)) as long as they are properly referenced in the OSRP. However, incidents, such as the Macondo Well blowout, demonstrate that source control activities need to be better coordinated with the overall management of the larger incident and other response operations, and they validate the need for additional source control information in the OSRPs. Accordingly, the OSRP should outline how the management structure established for the overall incident response will coordinate SCCE activities. BSEE believes the inclusion of this critical information in the OSRP will improve clarity for all responders rather than create confusion, and will not appreciably increase the size of the OSRP documents.

One commenter recommended the Arctic-specific regulations contain milestones that ensure timely deployment of well control equipment in concert with oil spill response equipment.

BSEE agrees and has determined the final rule addresses the commenter's recommendation. Regulatory requirements finalized in other parts of this final rule, such as §§ 250.470, 250.471 and 250.472, contain new standards for the deployment of well control equipment in the Arctic and include timelines for deployment. We note, however, that although the commenter's concern is addressed in part 250 of this final rule, part 254 currently does not contain any specific timelines for the deployment of spill response equipment.

Two commenters request that BSEE require plan holders to describe how they will respond in adverse weather conditions.

BSEE agrees. Existing § 254.26(d) requires plan holders to discuss how they will respond to their WCD scenario in adverse weather conditions. The purpose of subpart E is to provide additional regulatory detail to address Arctic-specific issues and challenges. The finalized requirements in § 254.70(b) require an operator to describe how they will address certain human factors, such as cold stress and cold-related conditions that are likely to become challenges due to the adverse nature of Arctic OCS conditions. Additionally, the finalized requirements in § 254.80(a) and (b) require an operator to describe how they will adapt and sustain their response techniques during adverse conditions that occur in the Arctic OCS operating environment.

One commenter recommended that operators be required to provide detailed statistical assessments for identifying curtailment thresholds that will limit operations or pose safety hazards to responders in Arctic conditions, and that this assessment should be used to establish the end of season operational dates at § 550.220(c)(6).

BSEE agrees in part. Section 254.70(b) requires operators to describe how they will address Arctic challenges in adverse weather conditions. While it is prudent for operators to identify and address recommended operating limits in their safety procedures, decisions to suspend response operations due to safety concerns must be made on a case by case basis and must consider all the conditions in place at that point in time. Operational safety decisions cannot be projected forward based on a statistical analysis of past seasonal conditions; however, the general limitations on an operator's' ability to conduct an oil spill response due to expected site conditions are considered by BOEM when establishing end-of-season dates.

One commenter suggests the requirements of § 254.70 should be more performance-based and focus on management practices.

BSEE agrees in part. The OSRP regulations are designed to strike a balance between performance-based standards that afford an operator the flexibility to develop an OSRP that meets the specific needs of its offshore facility and more detailed prescriptive requirements ensuring an OSRP meets the underlying statutory requirements. Many of the provisions contained throughout part 254 are performance-based in nature, while many others address the management practices of the operator to organize and respond to their WCD. BSEE believes that § 254.70 appropriately strikes that balance as written.

One commenter asserted that the provision in § 254.2(b), which allows a facility to operate while BSEE reviews the plan, should be removed for operations in the Arctic OCS.

BSEE agrees in part, however the proposed rule did not contain any amendments to the requirements of § 254.2. These administrative practices have been successfully followed for many years for OSRPs in other OCS regions, and are particularly well suited for certain situations, such as the transfer of ownership of an existing facility to a new operator who will now operate the facility under the new owner's existing regional OSRP. BSEE acknowledges that the provision in § 254.2(b) is not as well suited for the review and approval of new OSRPs covering exploratory drilling in the Arctic, where the challenges associated with operating in this frontier environment have made the review and approval of OSRPs more complex and controversial in the public eye. As such, BSEE will look to clarify the overall applicability of these procedures in a separate rulemaking that will update Part 254, including § 254.2. Finally, it should be noted that all operators on the Arctic OCS in recent years have had their OSRP approved well in advance of conducting any drilling operations at their lease sites.

One commenter asserted that all existing OSRPs should be updated to meet the new requirements of this rulemaking within 90 days.

BSEE disagrees. The final rule states that the requirements contained in this rulemaking will become effective 60 days after the date of publication in the **Federal Register**. At the time of finalizing this rulemaking, there currently are no approved or pending OSRPs involving exploratory drilling on the Arctic OCS from a MODU.

What additional information must I include in the "Emergency response action plan" section for facilities conducting exploratory drilling from a MODU on the Arctic OCS? (§ 254.80)

BSEE also proposed to create a new § 254.80 focusing on additional information requirements for the emergency response action plan section of an OSRP when the operator proposes to conduct exploratory drilling operations from a MODU on the Arctic OCS. The additional requirements would include specifics regarding ice intervention practices, staging considerations, and tracking abilities.

Several comments were received on this section. BSEE has evaluated the comments and made various technical edits as discussed herein. Otherwise, the substantive provisions of § 254.80 are finalized as proposed.

Many commenters assert that the regulations must include requirements ensuring Arctic-grade response capabilities for equipment, materials and personnel capable of operating in Arctic conditions, including fog, adverse sea states, and ice.

BSEE agrees and has determined this recommendation is met in our existing regulations. Section 254.26(e) states that operators must ensure that the response equipment, materials, support vessels, and strategies listed are suitable, within the limits of current technology, for the range of environmental conditions anticipated at your facility. Furthermore, § 254.80(a) requires that operators, who are developing ice intervention practices, must consider the use of specialized tactics, modified response equipment, ice management assist vessels, and technologies for the identification, tracking, containment and removal of oil in ice.

One commenter requested that BSEE delete the requirements of proposed § 254.80 as redundant to existing regulations in part 254. The commenter asserted that the requirement for ice intervention practices is redundant with the requirements of existing § 550.220(b), which requires an Ice Management Plan (IMP), a component of the Critical Operations and Curtailment procedures, and that the OSRP should simply reference the procedures contained within the IMP.

BSEE disagrees. The proposed requirements in § 254.80 address aspects of oil spill response preparedness, as opposed to operational preparedness, that are specific to meeting the challenges of operating in the Arctic OCS. While the requirements finalized here somewhat mirror the basic oil spill preparedness requirements existing in the OSRP regulations, they are not redundant of the IMP and add an important layer of additional detail that is necessary to set expectations for preparedness to respond to spills in the Arctic. The IMP addresses how ice floes will be managed to protect drilling operations and procedures for stopping, and if necessary, disengaging, drilling operations due to the encroachment of sea ice. Ice intervention practices have a completely different purpose, and are focused on improving the effectiveness of spill response countermeasures in the presence of sea ice. Both are distinct and necessary elements of the regulations.

One commenter recommended that ice intervention practices should address how response equipment will address challenges associated with response in the Arctic.

BSEE agrees. The intent of the requirement for a description of the operator's ice intervention practices was to ensure plan holders evaluated their capabilities and ensured they are adequately prepared and trained to effectively operate in expected Arctic conditions.

One commenter asserted that the requirement for ice intervention practices is limited to mechanical recovery.

BSEE disagrees with this statement, and reiterates that the operator should develop ice intervention practices for each response countermeasure listed in the OSRP. The preamble discussion in the NPRM states that an operator's ice intervention practices should improve oil encounter rates for all removal or mitigation techniques, including dispersants and in situ burning.

One commenter asserted that BSEE should conduct further studies regarding the challenges involved with responding to a spill in the Arctic, such as responding in the presence of ice.

BSEE agrees and is continually reviewing ongoing research study reports as well as funding numerous studies of its own to better understand all aspects of responding to oil spills in Arctic conditions. BSEE uses that information to better inform its efforts to develop regulations and assess a plan holder's preparedness to respond to oil spills.

One commenter recommended that, in addition to requiring the development of ice intervention practices, BSEE provide specific recovery equipment performance standards for recovering oil in the Arctic. Specifically, the commenter recommended that BSEE adopt a standard similar to the State of Alaska requirement at 18 AAC 75.445(g)(5).

BSEE agrees with the intent of the comment, but has determined the commenter's concern is addressed in existing regulations. BSEE reviewed the standard contained within 18 AAC 75.445(g)(5) and found that the existing requirements in § 254.44 already establish an equipment performance planning standard that is equivalent in nature. In addition, BSEE has an ongoing regulatory study underway to evaluate potential revisions to the requirements contained in § 254.44, including a revised equipment planning standard that would be based on oil encounter rate and recovery system-based performance. This revised planning standard may be incorporated into the regulations for all OSRPs, including those in the Arctic OCS, at a later date in a future rulemaking.

Several commenters recommend the provisions in the Arctic-specific regulations should be informed by research into oil behavior and spill response techniques in ice, and that flexibility must exist to select the most effective strategies in context of the spill situation.

BSEE agrees with both of these points. Both government and industry are conducting extensive research on oil behavior and the use of appropriate spill response techniques in ice. BSEE's development of its regulatory requirements, as well as its plan review and approval processes, is informed by this information. BSEE also supports the use of a process to compare the environmental outcomes associated with using various response techniques and countermeasures in order to assess and select the most appropriate response technologies for use during an event. However, the selection and use of response technologies during a spill event is governed by EPA regulations contained within the NCP, and by the FOSC, which is a pre-designated senior USCG official. BSEE is not dictating the selection or use of any particular strategies for responding to any specific spill situation through its regulations or the OSRP process.

One commenter suggested that OSRPs should include information that outlines when dispersants will be used and when their use will not be allowed.

BSEE disagrees. A plan holder does not have the authority to prescribe the conditions or required outcomes that must be present for dispersants to be used during a response. The use of dispersants is governed by the provisions of the NCP, as supplemented by RCPs and ACPs, and implemented on a case by case basis under the direction of the FOSC.

One commenter asserted that the OSRP regulations currently limit the response to mechanical spill recovery techniques only, and that BSEE should allow plan holders to use other response countermeasures when their use is appropriate. The commenter also indicated that the OSRPs should describe how those countermeasures will be used in the presence of sea ice and other Arctic conditions.

BSEE agrees that plan holders should plan for and prepare to use all available technologies and countermeasures to effectively mitigate the impacts of a discharge from their facilities, and that such planning and preparation should account for the presence of sea ice and other Arctic OCS conditions. While the regulations require the inclusion of mechanical recovery resources in the response plans, the regulations also allow for the listing of dispersants, in situ burning, and other response countermeasures in the plans, when using those countermeasures would be consistent with the strategies contained within the RCPs and ACPs for the area in which the facilities are operating. The procedures in the RCPs and ACPs provide the processes that a plan holder and the FOSC must follow in selecting the proper response countermeasures for a given situation. BSEE also agrees that OSRPs for facilities operating in the Arctic should describe how the plan holder would implement each countermeasure in ice. The new requirement to describe ice intervention practices in § 254.80(a) requires the plan holder to describe how they will effectively use each countermeasure in the presence of sea ice.

One commenter recommended that strategies and tactics listed in the OSRP, including use of dispersants and burning, should be based on the latest regional-specific research, historical oil spill data, field tests conducted by the operator or its Oil Spill Response Organization (OSRO), and exercises, and environmental analysis.

While BSEE agrees that response strategies and tactics should be informed by all the methods recommended by the commenter, BSEE disagrees with their assertion that plan holders are responsible for gathering this information, or that plan holders are responsible for field testing or validating these strategies and tactics as part of the process of developing and submitting their OSRPs. Rather, response strategies and tactics are developed and approved for use geographically and temporally, and should be exercised and validated by the Regional Response Teams and Area Committees, and should be contained in the appropriate RCPs and ACPs. As such, Regional Response Teams and Area Committees would be the appropriate entities to review ongoing trends, new research or testing information, and to adjust the response strategies in the RCPs and ACPs accordingly. While OSRPs must be consistent with the strategies and tactics identified for use in the relevant RCPs and ACPs, their focus and purpose is to address how the operator will supply, manage, and sustain the necessary response resources for implementing the strategies and tactics.

Two commenters recommend that the requirements in § 254.80 should contain specific protection and response strategies and maps for environmentally sensitive areas and subsistence resources. One of the commenters further suggests that plan holders should have response personnel and equipment pre-staged near those sensitive sites, and that the strategies and equipment should be tested through a plan holder's exercise program, prior to being included in an OSRP.

While BSEE agrees protection and response strategies for sensitive resources are a critical part of oil spill response, BSEE disagrees that these strategies should be developed by industry plan holders, nor does BSEE believe it is feasible for a plan holder to pre-stage personnel and equipment throughout the Arctic wherever sensitive resources might be located. The correct place for the development of protection and response strategies for sensitive areas and resources, in accordance with guidance in the NCP, is in the ACP. In this case, the appropriate place would be within the North Slope SubArea Contingency Plan. Existing regulations do, however, require that operators address strategies for protecting environmentally sensitive areas in their OSRPs. *See, e.g.,* §§ 254.23(g) and 254.26(c). BSEE does not believe that further treatment of this issue is necessary in § 254.80. The Alaska Regional Response Team and the North Slope SubArea Committee are responsible for testing and validating these strategies. It is not the responsibility of an industry plan holder to develop these geographical response strategies, nor is it a requirement for a plan holder to test any strategies listed in an ACP prior to referencing them in their OSRP.

One commenter requested clarification regarding what areas under section § 254.80(b) would qualify as "areas of the Arctic OCS where a planned shore-based response would not satisfy § 254.1(a)." This commenter also requested clarification of the term "remote and limited infrastructure" under § 254.80(b)(2), indicating that this term is ambiguous and could change based on location and the future progress of the Arctic infrastructure on the coastline.

BSEE acknowledges there is a subjective element to these provisions that must be evaluated by the plan holder and agency plan reviewers on a case-by-case basis. The intent of the provisions is to ensure that plan holders take the steps necessary to ensure they can mobilize and sustain a significant oil spill response effort in the Arctic and overcome the obstacles presented by the extremely limited infrastructure that exists throughout the entire Arctic region. Given the development along the Arctic coast, the entire Arctic OCS region would qualify for both provisions. BSEE acknowledges this situation could change in the future, and thus adopted language that would allow the application of these provisions to evolve once an appropriate level of infrastructure is developed and put in place. BSEE can document and communicate such situations in the future through an NTL or other communications with plan holders as such need arises.

One commenter asserted that situations where an entirely offshore-based response is necessary, with no support from onshore resources, are not unique to the Arctic.

BSEE agrees this situation does exist, to a degree, for certain facilities located far offshore in the Gulf of Mexico. However, in the Arctic, unlike the Gulf of Mexico, nearly all OCS exploratory drilling falls into this offshore-based category due to the lack of shore-based supporting infrastructure in the region. As such, BSEE believes it is appropriate to have specific planning requirements to address this aspect of responding on the Arctic OCS.

One commenter suggests replacing the phrase "adverse weather conditions" in § 254.80(b)(1) with the concept of "realistic maximum response operating limits" (RMROL) from 18 AAC 75.425(e)(3)(D).

BSEE agrees plan holders must research the environmental conditions for the Arctic OCS area they will be operating in and ensure that the resources they acquire will be capable of sustained activity in those conditions; however, BSEE does not intend to establish specific operating criteria or limits for such equipment. The requirement for response equipment to be capable of operating in conditions up to and including adverse weather is a longstanding element of OPA requirements and is sufficiently covered by other parts of BSEE part 254 regulations. While the ability to operate in adverse conditions is an important element of § 254.80(b)(1), the real purpose of this requirement is to establish an offshore-based capability that can function without constant resupply from shore side infrastructure.

One commenter asserted that requiring the pre-staging of response equipment reduces the flexibility of the incident commander to respond effectively.

BSEE disagrees. Pre-spill planning, including the identification of pre-staging sites, is critical to an effective incident response. Incident commanders always have the flexibility to adapt the pre-spill planning in the OSRPs to meet the emergent needs of responders during a real incident. Therefore, BSEE does not believe that pre-staging response equipment reduces the flexibility of the incident commander to respond effectively.

One commenter asserted that additional response resources and training of local responders are needed along the coast of the State of Alaska. One commenter recommended that agencies with oil spill response responsibilities study various locations along the U.S. Arctic coast where equipment could be stored and staged, suggesting that such emplacements would lead to improved response times for equipment and potentially reduced the environmental impacts of an oil spill.

BSEE agrees that staging of equipment at strategically located depots along the State of Alaska coast could have a positive impact on oil spill responses that occur in the Arctic. However, the staging of response resources is primarily dependent upon the needs of each individual plan holder to enable them to respond to their WCD. As such, staging of response resources falls to the discretion of the plan holder and their OSRPs, with agencies reviewing their arrangements to ensure they will meet the planning standards in the regulations. To provide flexibility in allowing plan holders to meet their individual needs, the regulations do not mandate the use of any particular staging location(s) for equipment and personnel that must be used to meet response planning standards.

One commenter asserted that all response resources should be located in the Arctic prior to the start of drilling operations unless a viable logistics plan is in place for cascading in additional response supplies.

BSEE agrees. Paragraphs (a) and (b) of § 254.80 require operators to list and describe their resources that will be offshore-based in the immediate area of the drilling operations, as well as their logistics resupply chains that will effectively address the remote and limited infrastructure that exists in the Arctic.

One commenter recommended the OSRP contain requirements for pre-staging equipment in the Russian Arctic, as well as procedures for moving response resources into waters under the jurisdiction of Russia.

BSEE disagrees. The preparedness and response requirements related to an oil spill located in Russian waters are governed by the laws and regulatory requirements of Russia. The movement of resources and the coordination of response activities between the two countries in the event of a transboundary oil pollution incident will be addressed by the U.S. Department of State and will follow existing bi-lateral and multi-lateral agreements that are in place for responding to transboundary spills in the Arctic.

What are the additional requirements for exercises of your response personnel and equipment for facilities conducting exploratory drilling from a MODU on the Arctic OCS? (§ 254.90)

BSEE proposed to create a new § 254.90 that would require operators to incorporate the additional requirements contained within §§ 254.70 and 254.80 into their oil spill response training and exercise activities; would require operators to provide notice of the commencement of covered operations; and would clarify the authority of the Regional Supervisor to conduct exercises, prior to and during exploratory drilling operations, to test response preparedness. These requirements are all essential to ensuring and verifying an operator's readiness to conduct response activities on the Arctic OCS.

Several comments were received on this section. BSEE has reviewed the comments and determined to finalize § 254.90 as proposed for the reasons stated herein.

One commenter recommended that operators conduct mandatory equipment demonstrations of response technologies under adverse conditions for operations that will occur in the Arctic Ocean.

BSEE disagrees. Under the requirements of the existing OSRP regulations and the implementing guidance contained within the PREP Guidelines, the operator must conduct equipment deployment exercises, without reference to the operating conditions, for the purposes of training, testing, or demonstrating the preparedness, material condition, and proficiency of personnel and equipment. These exercises are normally conducted under operating conditions that are conducive to achieving the deployment exercise objectives while maintaining a suitable margin of safety for all participants. BSEE does not believe that the increased risks associated with conducting exercises under adverse conditions are justified by an attendant increase in preparedness.

One commenter argued that a facility engaged in seasonal use in the Arctic will have difficulty complying with the regulatory exercise requirements, and that conducting equipment deployment drills that focus on ice intervention practices will not be of value during the open water season.

BSEE disagrees. Plan holders drilling only during the open water season have the same triennial period to comply with exercise and training requirements as all other operators. A plan holder may conduct their exercises and training when they deem most appropriate as long as they meet the regulatory requirements for the frequency of exercises. Incident management team and deployment exercises, designed to test ice intervention practices, may be done during the drilling off-season when ice is present if that is deemed a more valuable exercise. BSEE disagrees that equipment deployment drills focusing on ice intervention practices are not of value to operations during the open water season, as sea ice can be present throughout the year and would be very relevant to an early- or late-season spill response.

One commenter urges BSEE to remove the provision in § 254.90(c), under which the BSEE Regional Supervisor may require deployment of the capping stack, cap and flow system, and containment dome, and other similar subsea and surface devices and equipment and vessels, as part of announced or unannounced exercises or compliance inspections, due to the disruption it will cause to an already brief open water drilling season.

BSEE acknowledges the concern raised by this comment, and agrees that exercises of SCCE, if deemed necessary, should be conducted in a manner that minimizes disruptions to operations during the open water drilling season. BSEE will retain the provision in the rule to provide the Agency with the maximum flexibility possible to exercise its preparedness assessment and evaluation responsibilities, as necessary to demonstrate the operator's preparedness to respond during active operations. However, BSEE will ensure that SCCE deployment exercises are designed to minimize disruptions to the drilling season to the extent practicable.

One commenter recommended that any exercises directed by the Regional Supervisor should only occur after the plan holder has been notified and the particulars of the exercise have been discussed and agreed upon by all parties.

BSEE disagrees. While BSEE acknowledges the value of collaborative pre-planning in designing and holding exercises, BSEE reserves the discretion and flexibility to hold exercises in both announced and unannounced manners, as deemed necessary and appropriate, to assess and verify a plan holder's readiness and spill response preparedness. The operator's ability to execute its spill response operations with the limited notice that would be afforded in a real-word spill scenario is a critical aspect of that preparedness. BSEE will notify in advance and collaborate with plan holders in designing exercises whenever practicable when such procedures are in alignment with BSEE's exercise and overall compliance objectives.

One commenter opposed the provision for exercising equipment deployment requirements for SCCE and recommended it be removed due to the costs and operational risks involved, and the lack of specificity regarding these requirements in the regulations.

BSEE acknowledges equipment deployment exercises of SCCE are likely to be costly and may involve increased operational risks. Currently there is no recurring equipment deployment exercise requirement for SCCE outside of being directed to do so by the Regional Director or the Chief of the Oil Spill Preparedness Division of BSEE. Due to the increased costs and risks associated with this activity, BSEE intends to use this authority only when it deems it absolutely necessary to verify a plan holder's preparedness.

One commenter asserted that the provision in § 254.90(c) allowing the Regional Supervisor to direct the plan holder to deploy and operate spill response equipment or SCCE as part of an exercise or compliance inspection is contradictory to the information contained within the PREP Guidelines and MOA OCS–08, and therefore should be revised.

BSEE disagrees. The PREP Guidelines and USCG/BSEE MOA OCS–08, *Mobile Offshore Drilling Units (MODUs),* provide additional guidance on how existing regulatory requirements are to be implemented. Any new requirements promulgated in a rulemaking would take precedence over contradictory content in the PREP Guidelines. However, it is BSEE's position that the requirements in this rulemaking and the language expressed in PREP and in the MOA are in alignment with respect to BSEE's intended posture for exercising SCCE as a capability listed in a plan holder's OSRP. BSEE views the deployment of SCCE as a demonstration of a response capability necessary to secure and mitigate the threat of a potential or actual discharge of oil. Until such time when new regulatory requirements for conducting deployment exercises of SCCE are promulgated in Part 254, BSEE will continue to implement the exercise compliance posture as it has been outlined in the PREP Guidelines.

Two commenters oppose finalizing the requirement for BSEE to direct a plan holder to mobilize and deploy equipment during an exercise because it will cause confusion over who has oversight authority to direct a response during an actual spill.

BSEE disagrees with this comment. The requirement in § 254.90(c) only applies to BSEE directing the deployment of response equipment in an exercise for the purposes of evaluating a plan holder's preparedness, and does not apply to a response during an actual spill. For any spill in the coastal zone, the USCG is the FOSC who has overall authority to direct oil removal operations. Further information regarding the respective coordination between the USCG and BSEE for both preparedness and spill response activities is found in USCG/BSEE MOA OCS–03, *Oil Discharge Planning, Preparedness and Response.* BSEE does not believe requiring the deployment of response of equipment for the purposes of an evaluation will result in confusion during an actual spill.

One commenter requested that the proposed revisions to part 254 apply to all operations on the Arctic OCS.

BSEE disagrees and this comment is beyond the scope of this rulemaking. While BSEE acknowledges that certain regulatory provisions would be beneficial for non-exploratory Arctic OCS activities, such provisions are beyond the scope of this rulemaking. BSEE will consider extending Arctic-specific provisions to other operations, such as drilling from gravel islands, or oil production activities, in a future rulemaking.

One commenter suggested the requirements for conducting exercises should be more specific regarding the timing of such exercises.

BSEE disagrees. Beyond the established frequency requirements in the regulations and in the PREP guidance, the timing of conducting planned exercises is left to the discretion of the plan holder in order to allow them to develop an integrated and effective exercise, equipment maintenance, and training cycle that meets their needs.

C. Discussion of Comments on the Initial RIA

Comments on the initial RIA generally related to the exploratory drilling scenario, cost factors used, baseline assumptions and benefits. BOEM/BSEE revised cost factors or assumptions and expanded the discussion of qualitative benefits for the final RIA. The comments received, information provided by commenters and whether changes were made in the final rule RIA is discussed herein.

Revised Assumptions

Several commenters question the assumptions about future levels of industry activity in the Arctic OCS contained in the initial RIA.

We acknowledge the commenters' concern. In accordance with recently announced changes in future Arctic exploration plans, such as Shell, ConocoPhillips and Statoil's decisions to suspend exploration activity offshore Alaska, BOEM and BSEE have revised the exploration scenario in the final RIA.[45] The scenario assumptions have been updated to reflect the relinquishment and termination of many Chukchi and Beaufort leases. BOEM and BSEE's level of expected Arctic OCS exploration activity has been maintained, however the beginning year is no longer assumed. The rulemaking exploration scenario aligns activity with numbered years instead of calendar years. The result is that the Bureaus are not estimating when exploration may begin, but rather the likely activity when it does resume. Acknowledging the temporal uncertainty of future Arctic exploration allows the public to focus on the potential compliance costs and benefits of the rule. The final RIA's activity assumptions represent an aggressive exploration scenario which presents a likely maximum of the compliance costs expected from this rule over the 10 numbered years once Arctic exploration is resumed.

The proposed rule's scenario spanned from 2015 to 2024. The final RIA scenario spans from year 1 to year 10. Activity assumptions are based upon a number of variables that are difficult to predict, including the willingness of operators to invest in conducting such operations, the availability of assets required to conduct operations, and a number of other issues. BOEM and BSEE have made these assumptions to ensure that they do not understate costs associated with the final rule. The scenario, therefore, includes 10 years with 9 years of active exploration and 50 wells drilled.

Additionally, the exploration activity scenario no longer includes an idle relief rig. During the 2015 drilling season, Shell sought to use two drilling rigs at different sites and to designate each rig as the relief for the other. Because of legal restrictions, Shell ultimately only used one rig to conduct drilling operations; the second rig remained idle during the drilling season. That rig, however, was contracted to perform drilling operations and was located at a potential second drilling site. We have concluded that, with clear regulatory requirements in place, an operator in the future is most likely to productively employ all rigs for active exploratory drilling rather than have an idle relief rig. Consistent with this fact we acknowledge the capital and operational expenditure for a second Arctic rig even though productively employed may not be a company's best use of its capital. It may prefer to explore elsewhere or deploy its capital on development projects rather than exploration. Companies are forced to employ a drilling rig for this potentially less efficient use of capital resources. Therefore, we acknowledge that it is not a cost free decision for operators and lessees.

BOEM and BSEE have adopted what we view to be conservative (*i.e.,* high side) projections of the Arctic OCS activities that can be reasonably anticipated. We assume for purposes of this analysis that three operators will be present on the Arctic OCS over the 10-year analysis period, with one operator conducting exploratory drilling beginning in year two and two additional operators commencing exploratory drilling in year 4. These assumptions reflect potential activity based on expectation for future Arctic leasing. For the total number of exploratory wells on the Arctic OCS, we assume four wells in year 2 and year 3 and six wells from year 4 through year 10. Additionally, the final RIA assumes that: (1) The number of wells drilled and the number of APDs submitted to BSEE will be equal for each year of the analysis period; (2) each operator will submit to BOEM an EP in the year prior to exploratory drilling; and (3) an IOP and OSRP will be submitted by each operator in each year prior to drilling.

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[45] Shell updates on Alaska exploration, September 28, 2015 press release, *http://www.shell.com/global/aboutshell/media/news-and-media-releases/2015/shell-updates-on-alaska-exploration.html.*

Two commenters question the difference between the initial RIA and the NPRM cost-effectiveness analysis as to the number of operating rigs. The commenter cites the initial RIA as assuming one rig operating in 2015–2016, two for 2017, and four rigs operating from 2018–2024, and the NPRM cost-effectiveness analysis assumes two rigs operating for 2015–2017 and then four rigs operating from 2018–2024. The commenter questioned the difference and concludes that the assumptions would result in a ten-year cost of $174 million based on the initial RIA, while using the number of operating rigs per year set forth in the NPRM scenario would result in a ten-year cost of $204 million. However, the commenter points to the average annual cost used in the initial RIA as being $19.2 million, which does not match the assumptions outlined in either document.

BOEM and BSEE are aware of the difference in the relief rig assumptions between the initial RIA and the NPRM cost effectiveness analysis. We decided to use assumptions in the initial RIA that would present the likely maximum level of compliance costs, which included assuming the presence of a dedicated standby rig for years 2015–2016. However, the final RIA assumptions render this difference moot. As described above, the scenario for future Arctic exploratory drilling operations has been revised. The rig counts throughout the RIA were revised for consistency. BOEM and BSEE no longer assume that operators will have an idle relief rig and instead assume that operators will have all rigs actively engaging in exploratory drilling. The revised Arctic exploratory drilling scenario has zero rigs drilling in year 1 (no operators actively drilling), two rigs drilling in years 2 and 3 (assuming one operator), and four rigs drilling during years 4 to 10 (assuming three operators).

One commenter questioned the assumption related to industry sharing oil spill response assets and believes costs should have been calculated on the basis of a single industry participant operating in the region. The commenter noted the costs were based on an assumption of modest growth in the number of operators in the region during the next decade, but if fewer operators seek to operate on the Arctic OCS, there will also be fewer opportunities for operators to enter into contractual agreements to share relief rigs and other oil spill response equipment. The commenter stated that, if this occurs, operators will need to furnish their own relief rigs and associated infrastructure, thereby driving up operating costs.

The revised assumptions used for the final RIA include years in which one operator is operating in the Arctic and other years in which multiple operators are engaging in Arctic exploration and can share resources. Annual costs show the range of compliance costs from years 2 and 3 when one operator must bear all of the costs to the later years when operators can engage in resource sharing. Even in the beginning of the scenario when a single entity operates, we assume that operator has two rigs with no standby relief rig, as all operators are assumed to actively engage all rigs in exploratory drilling. Regardless of the number of operators, whether it be one or more than one, additional operating rigs are assumed to be used even with sharing of resources. With three operators in year 4, the analysis assumes that there are four operating rigs. BOEM and BSEE's compliance cost calculations consider the vessels which can be shared between operators (*e.g.,* oil spill response vessels) and assume the one operator must pay for all of these services in years 2 and 3, but these costs are shared between operators in the later years. If we followed the commenter's assumption of only one operator, per-well costs would be higher, but the total compliance costs would be an underestimate of what they would be in the presence of multiple operators. The approach used in the final RIA analysis demonstrates the higher per well costs in the early years with only one operator, but also recognizes that resources can be shared in later years if additional operators enter the region.

One commenter questioned the Bureaus' assumption that only one operator will be operating through 2017, but that relief rigs would be cross-assigned between different operators to satisfy the requirement, meaning each operator's primary rig would be utilized by the other operator as a relief rig in the case of a well control incident. The commenter recommended the cost analysis for this time period should not be based on cross assignment between operators, as the Bureaus have provided no basis on which to assume an operator would bring more than one rig to the theater if not for the proposed relief rig requirement.

We no longer assume that an operator would bring more than one rig solely to serve as a standby relief rig. Instead, it is assumed that, during years 2 and 3 with one operator, the operator will have two operating rigs and will designate each rig as relief rig for the other. While it is possible that an operator may have only wanted to drill one well in the Arctic (thus not bringing a second rig if not for the relief rig requirement), we believe that, from an economic perspective, regardless of the relief rig requirement, it would be prudent for an operator to bring two rigs to the region. Given the large fixed costs of drilling in the Arctic (regardless of this regulation's new requirements), the marginal cost of a second rig would likely justify the operator to bring two rigs, in that they could share common support vessels, etc. The rig count scenario was revised for consistency in the final RIA.

One commenter questioned the initial RIA assumptions that two IOPs will be submitted in 2015, however only one EP will be submitted. The commenter requested that the Bureaus clarify under what circumstances more IOPs than EPs would be submitted in any given year, as the IOP requirement is tied to submittal of an EP. The commenter further questioned the initial RIA assumptions in Exhibit 3 showing three operators working on the Arctic OCS from 2018 to 2024, while the numbers of IOPs, EPs, and OSRPs are not in line with that number of operators.

BOEM and BSEE agree that the number of IOPs and EPs should be the same. The final RIA revises the IOP and EP assumptions from the proposed rule and initial RIA so that a single EP and single IOP per operator are submitted in the year prior to exploratory drilling.

Overestimated Costs

Several commenters assert that the cost assumptions in the initial RIA are significantly overestimated and many of the costs of the finalized regulatory provisions should be included as baseline costs. One commenter expressed concern that the initial RIA overstated the costs of the proposed rule by assigning existing baseline costs that operators already include in their budgets as incremental costs. The commenter noted that many of the regulatory provisions in this final rule codify existing industry practices or incorporate existing requirements imposed by the Department as a condition of plan approval, through an

NTL or as BAST) methods under § 250.107.

After reviewing comments, BOEM and BSEE have determined some of the costs identified as new regulatory compliance costs in the initial RIA are, instead, baseline costs. Costs are considered baseline if they are attributable to existing regulatory requirements, industry standards, and operator best practices. OMB's Circular A–4 ("Regulatory Analysis") directs that the baseline should be "the best assessment of the way the world would look absent the proposed action." BOEM and BSEE have broad authority under existing regulations to impose reasonable conditions on exploration plan approvals and drilling permits. Thus, the final RIA excludes from new compliance costs the activities or capital investments that existing regulations may require, as well as impacts resulting from the incorporation of industry standards with which the industry voluntarily complies.

The two provisions that are codified in this rulemaking and considered in the regulatory baseline are Additional Requirements for Securing Wells (§ 250.720) and Real-time Monitoring Requirements (§ 250.452). To supplement the analysis, we include a discussion of the baseline assumptions within the text of the final RIA and acknowledge the compliance cost for these two baseline provisions in the RIA appendix.

Compliance Cost Estimates

BOEM and BSEE considered all comments and revised the cost estimates for some provisions based on information provided in comments. Costs provided in comments were considered and greatly influenced the cost estimates used in the final RIA.

As mentioned above, the biggest change in the compliance cost of the rule relates to the characterization of costs, as BOEM and BSEE concluded that industry's existing practices and BOEM's and BSEE's current regulations would be used as the baseline for our analysis. To supplement the analysis, we included a discussion of the baseline costs within the text of the final RIA, and in developing the new compliance costs and estimates of the baseline cost, BOEM and BSEE seriously considered, and in many cases used, cost estimates provided by commenters that could be validated or were deemed reasonable.

Several commenters argue that the costs of the initial RIA were significantly underestimated and that the rule will result in a negative impact to America's economy and energy security by inhibiting oil and gas development on the Arctic OCS. One commenter asserted that the approximately $1 billion cost to industry estimated in the initial RIA over the 10 year assessment period fails to address the impacts of shortening the effective drilling season, driven primarily by the same-season relief well requirement. The commenter also argued the RIA uses assumed spread rates for drilling and emergency response facilities that are far lower than demonstrated by industry experience. The commenter asserted that the Bureaus' estimated costs in the initial RIA are drastically low, sometimes by several orders of magnitude, and that the cost to industry is $10–20 billion higher over the 10-year period. BOEM and BSEE generally disagree.

BOEM and BSEE considered these comments. The cost estimates provided comments influenced the compliance cost estimates for several provisions in the final RIA. In developing the new compliance costs and estimates of the baseline cost, BOEM and BSEE closely considered and in many cases used revised cost estimates provided in comments. The final RIA includes revised cost assumptions for each provision.

Regarding the assertion that our regulation of offshore oil and gas production in the Arctic will inhibit a large amount of economic activity, including preventing the creation of many new jobs, we disagree. Industry interest in potential development in the Arctic OCS region of Alaska is largely driven by the price of oil and gas and the challenging and harsh conditions in the area, as evidenced by recent departures from the area by Shell and Statoil. As a result, the Arctic OSC region of Alaska has not previously relied on the type of offshore drilling regulated by this final rule for economic development or well-being. The OCSLA states that the policy of the U.S. is to both make the OCS available for production and development as well as to ensure that operations are conducted safely. Lessees, particularly in the Arctic, obtain OCS leases and pursue exploration with a full understanding of this dynamic. This rulemaking reflects the Bureaus' reasonable and appropriate fulfillment of their multifaceted OCSLA mandates.

In addition, the final regulations could bring potential benefits to the local economy and cultural traditions from reduced risk of oil spills. A catastrophic oil spill would have negative economic impacts far beyond the offshore oil and gas industry. A catastrophic oil spill could disrupt subsistence practices, such as whaling, on which Native Alaskans rely for food and for their cultural preservation.

One commenter asserted that the initial RIA incorrectly estimates the daily per-rig operating cost at $2 million because it fails to take into account that rigs and vessels contracted for Arctic exploration are contracted on an annual basis. The commenter further states that, by considering the operating costs for a single day via day rates based on 365 days per year of utilization, the Bureaus have understated significantly the cost of a drilling day lost due to regulatory requirements or constraints. The commenter recommended that the cost should be captured in a weighted daily estimate of operating cost tied to the shortened Arctic operating season. The commenter noted that, based on an estimated 100 drilling days available in the Chukchi Sea, this results in an effective daily operating cost of $7.5 million per day per rig when the full cost of 'ownership' is taken into account. Due to the significant fixed cost burden, the commenter asserted that the cost of a day spent not operating can be estimated at 80 percent of the operating rate, or $6 million per rig per day.

BOEM and BSEE have addressed this comment in the final RIA by adjusting the daily rig operating costs to $3.97 million, which assumes the operating rig must be contracted for the entire year and supporting vessels for part of the year. To address lost drilling days, the compliance cost of the "shoulder season"[46] is also estimated. It is assumed that the shoulder season requirement will shorten the drilling season by 34 days, out of the estimated 116-day drilling season. This 29 percent reduction in drilling days is used to estimate that 29 percent of the annual cost of the drilling rig is lost due to this provision. There are also savings realized during the 34 days from support vessels demobilizing 34 days earlier. BOEM and BSEE also note that operators may still undertake productive activities on wells during the shoulder season. However, to provide maximum estimate of potential cost of the shoulder season, these benefits are not considered in the estimated cost. The final RIA estimates the annual shoulder season costs as $84.42 million in years 2 and 3 and $177.95 million per year in years 4 to 10.

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[46] The shoulder season is the period of time operators may not drill or work below the surface casing, and its length is dependent on an operator's ability to demonstrate the capability of the relief rig to arrive on site, drill a relief well, kill and abandon the original well and abandon the relief well prior to expected seasonal ice encroachment at the drill site.

One commenter disagrees with the initial RIA's assumption that the operating season on the Arctic OCS is 138 days long and asserted the Bureaus have exaggerated the season length and incorrectly spread costs across a greater number of days, resulting in the overall cost impact being incorrectly reduced. The commenter asserted that current regulatory constraints make July 1 to October 31 the highest potential estimate for season length (totaling 123 days), while ice data collected over the last 10 years would indicate an average season length of approximately 100 days. The commenter questioned whether the Bureaus have either assumed operators will have access prior to July 1, which is prohibited by current USFWS regulations, or extended the season past October 31, which is not supported by historical ice data.

BOEM and BSEE agree and have used assumptions that reflect a drilling season reduced to 82 days long. BOEM and BSEE estimate the ice-free season to be 116 days long (from July 7 through October 31) and subtract 34 days for the baseline shoulder season.

Two commenters questioned the cost of familiarization with the requirements of this rulemaking. One commenter asserted that the time estimated in the initial RIA for industry staff to generate the information was understated and allocated incorrectly to managerial time, when the work would be done by mid and senior level engineers. Another commenter stated that their experience with implementing rule packages for operations necessitates an initial time commitment involving a number of people across a number of teams, resulting in a time commitment 50 times as large as that assumed in the initial RIA. The commenter added that there would be an ongoing need to onboard staff and contractors, resulting in 250 hours of labor per year for review in subsequent years.

BOEM and BSEE agree in part. In the final RIA we revised the estimated staff times required by industry for familiarization with the regulation. It is assumed for each operator that a senior engineer will spend 250 hours to review the new regulation. It is also assumed that each operator will spend 120 hours per year assuring new personnel's familiarity with the rule to prepare for the next drilling season.

Several commenters question the benefits analysis of the initial RIA, and many specifically cite to benefits being calculated based on the conditional assumption that a catastrophic oil spill will occur on the Arctic OCS in the next ten years. Commenters assert this assumption is at odds with the broadly acknowledged understanding, as stated in the NPRM, that the probability of such an event is extremely low. One of the commenters noted the initial RIA calculated the benefits of the regulatory action by assuming costs based on the clean-up of the 2010 Macondo spill in the Gulf of Mexico, but that the estimated oil released at Macondo was twice the "worst-case discharge" projections for any Chukchi Sea oil spill. Three of the commenters question the initial RIA benefits analysis as being inconsistent with the February 2015 Chukchi Sea Lease Sale 193 Supplemental Environmental Impact Statement. They suggest that the final RIA should align to the less than one percent chance of a large oil spill during exploration of the Arctic OCS.

BOEM and BSEE have determined the benefits of the final rule justify the costs when qualitative factors are considered. The potential impact and cost of an Arctic OCS oil spill is substantial. This rule's spill control mechanisms provide significant potential benefits through avoided spill costs. This justification relies on both qualitative and quantitative analysis. BOEM and BSEE acknowledge previous studies which have found the estimated probability of a catastrophic oil spill to be very low; the final RIA provides frequency estimates for large oil spills, but it is usually true of catastrophic risks that society deems it worthwhile to defend against them or be prepared to remedy them despite the low probability of the event. The American public greatly values the Arctic. It is viewed as a pristine, unspoiled environment. With this in mind, a catastrophic oil spill would have severe impacts and it is meaningful to examine the highly unlikely scenario of a catastrophic oil spill.

Given both the low probability and high consequence nature of a catastrophic oil spill, and after review of public comments, BOEM and BSEE did not conduct a break-even analysis on the provisions in this final rule. Such an analysis could misrepresent both the underlying risk of a spill and the magnitude of costs which could result. The Initial RIA included a break-even analysis which was conditional on a catastrophic oil spill occurring. This analysis was removed, in part, as a response to comments which suggested that such an analysis was flawed and implied that a catastrophic oil spill would occur in the Arctic without the new regulations. Instead, the RIA provides estimates of the probability of a catastrophic oil spill and the range of potential costs of various size catastrophic oil spills. If the regulatory provisions were able to prevent a catastrophic oil spill, the benefits of the avoided spill costs have the potential to far exceed the rulemaking costs. In addition, the RIA discusses the spill control mechanisms in the rule which have the ability to limit spill costs and monetizes the potential avoided costs from each provision. Together, this information identifies the substantial benefits of the rule in avoiding the costs of a catastrophic oil spill while acknowledging the underlying low probability of a spill.

BOEM and BSEE analyzed the specific provisions of this regulation designed to reduce the length of a catastrophic oil spill. The analysis focuses on the conditional state where a spill is assumed to occur within the 10-year scenario. BOEM and BSEE used historical data on oil spills to estimate the potential costs that would result from spills of various durations in the Arctic OCS region. BOEM and BSEE then used the final rule costs and the avoided damages of potential spills to estimate the possible rulemaking benefits. The initial RIA expressed the break-even analysis results in terms of the number of days of spilled oil that would need to be avoided for specific provisions of the regulation to be cost-beneficial. The final RIA includes an expanded discussion of potential avoided spill costs by spill control mechanism and the qualitative benefits of the regulation.

One commenter requested the final RIA strengthen its "Benefits" analysis by estimating the safety benefits, and not just the environmental benefits, of the proposed rule. The commenter noted that, if major oil spills are prevented by the rulemaking, there clearly would be safety benefits as well.

In response to comments received about the safety benefits, BOEM and BSEE expanded their discussion of this topic in the benefits section of the RIA, including a discussion on the importance of codifying existing industry standards and practices. These benefits result from the rule's requirements that reduce the probability of a catastrophic spill from a well control event and reduce the duration of a spill should one occur. Both of these reductions will increase safety in addition to their environmental benefits. The RIA considers the benefits of increased safety by considering the avoided costs from human fatalities and injuries that could occur during a catastrophic well control event and spill.

IOP Cost Estimates (§ 550.204)

One commenter questioned the initial RIA calculation of staff time required to develop the IOP for submission, and asserted the time is underestimated by almost a factor of 40. The commenter estimates the costs of this provision to be $793,212 annually, instead of the $125,167 annual cost cited in the initial RIA.

In response to this comment, BOEM revised the estimate of hours needed to prepare an IOP. The number of hours mid-level engineers spend to compile and include the required information in the IOP is revised to be 2,880 hours, resulting in a cost to industry of $281,721 per IOP, which is an increase from the initial RIA.

EP Cost Estimates (§ 550.220)

One commenter stated the initial RIA underestimates the amount of time required to develop the additional information required for submission of the EP by more than a factor of 20. The commenter assumed that 1,050 hours of industry staff time and 144 hours of agency staff time will be required, resulting in total average annual costs of $215,815. The initial RIA assumed 45 hours of industry staff time and 144 hours of agency staff time, resulting in average annual costs of $28,702. The commenter contends that development of the EP is a time intensive effort requiring input from a wide range of teams across the company to fully incorporate all of the information required by regulation.

BOEM finds the commenter's estimate reasonable for compiling and submitting the required information from different expertise areas. The required EP information includes descriptions of different operator emergency and contingency plans, information on suitability for Arctic OCS conditions, ice and weather management, SCCE capabilities, deployment of a relief rig, resource sharing, and anticipated end-of-season dates. The industry staff time assumptions in the final RIA match the estimate provided in this comment. Mid-level engineers are estimated to spend 1,050 hours compiling the required information for the EP. Multiplied by the median hourly compensation rate for mid-level engineers, the estimated industry cost is $102,711 per EP. The cost to BOEM remains the same at $10,898 per EP.

Incident Reporting Cost Estimates (§ 250.188)

One commenter identifies two issues with the costs and burden associated with the incident reporting provisions of proposed § 250.188. First, the commenter noted the difference between the initial RIA accounting for one rig in 2015 and 2016 and the NPRM analysis that accounted for two rigs each of these years. From this, the commenter concludes that there would be a doubled cost for 2015 and 2016 if the analysis in the final RIA were updated to align with the assumptions of the NPRM analysis. Second, the commenter questioned the number of hours of staff work required to compile and document the required information. Based on the commenter's own previous experience during the 2012 season, the commenter estimated that instead of 5.5 hours of mid-level engineer time as a cost to industry, each incident would require 50 hours. The commenter supports the estimate by stating that a multidisciplinary team would work together to gather the necessary information, and the time estimates should account for the time required to review and prepare the submission by a senior level engineer, which is estimated to be 50 percent of the time required to gather the data, resulting in an additional 25 hours of cost. The commenter noted that for the cost to the agency, the relationship of 50 percent of the time required to gather the data being required to review the submission was maintained, resulting in 25 hours of review time for the agency.

In the final RIA, the assumptions regarding staff time are revised for this provision. It is assumed that incidents having new reporting requirements the final rule will occur two times a year for each rig. Industry mid-level engineers will spend 50 hours and industry senior engineers will spend 25 hours on reporting requirements for each incident. It is assumed that a BSEE senior engineer will spend 25 hours reviewing each submittal.

Pollution Prevention (§ 250.300)

One commenter argued the initial RIA did not consider the operational and logistical burdens and costs associated with zero discharge operations for petroleum-based muds and cuttings. The commenter also argued the initial RIA did not account for costs associated with the authority of BSEE's Regional Supervisor to direct operators to capture water-based muds and cuttings, which will require operators to take into account that BSEE may drastically modify operations without warning, and the operator must plan accordingly. The commenter stated the initial RIA also did not account for any costs associated with the modification of rigs to handle a collection system, containers to collect and transport the muds and cuttings, vessels to transport the resulting volumes, or costs for the disposal of the mud and cuttings. The commenter asserted that an analysis of costs associated with Shell's 2012 Beaufort campaign, as well as updated plans based on what was learned from that campaign, demonstrate one-time costs required to prepare rigs and support vessels for a collection system. The commenter also identified additional operating costs for the rig system and for the collection, storage, and transport systems, which it states should all be included in compliance cost estimate for this provision.

The commenter disagrees with the initial RIA assumption that a skilled laborer on the rig crew and an industry senior engineer would spend, respectively, 60 and 8 hours annually to transport and dispose of mud and cuttings, resulting in an annual labor cost of $4,245 ((60 hours × $56.86) + (8 hours × $104.22)) per rig. The commenter proposes an alternative cost estimate for this provision as follows: $10 million to modify an existing rig and equipment for zero discharge operations; $2 million (annual cost per rig) to operate additional equipment on the rig; $3 million in upfront logistics costs per rig supported; and $14.5 million in annual logistics costs for the transport and disposal of waste. Taking into consideration the assumptions in the initial RIA Exhibit 3, the total cost of this provision would be $52 million in one-time costs to modify each rig and each rig's supporting logistic assets, and $561 million in total operating costs over 10 years, resulting in a total 10 year cost of $613 million.

BOEM and BSEE considered the comments received on the pollution prevention requirements and updated portions of the RIA accordingly. Based on other comments received and additional analysis conducted by the Bureaus, the final RIA assumes that the requirement to capture all petroleum-based mud and cuttings under this provision is in the baseline. The capture of petroleum-based mud and cuttings is an established industry practice and is required separately by EPA as part of the applicable NPDES permits. As this requirement is imposed separately by EPA, BOEM and BSEE do not include a cost for the capture of petroleum-based mud and cuttings as a cost of the rule.

BOEM and BSEE do consider the Regional Supervisor's discretion to require the capture of water-based muds and cuttings to result in costs attributable to this rule and have added an estimate of these costs to the final RIA. These costs are not considered as part of the baseline because the capture was not a condition of either the 2012 or 2015 exploration plans. Rather, Shell voluntarily negotiated with whaling captains and agreed to capture water-based muds and cuttings as part of its 2012 Beaufort Sea exploration program. We note that the final rule does not explicitly require the capture of water-based muds and cuttings and instead gives the Regional Supervisor discretionary authority to require it based on various factors, including the protection of marine mammals, fish, and their habitat, and negative impacts to subsistence activities. Accordingly, these estimated costs in the final RIA may be overstated because of the possibility that capture will not be required. However, we have determined to include these compliance costs in the final RIA because, in addition to the fact that the capture of water-based muds and cuttings was not a condition of the 2012 or 2015 exploration programs, the likely proximity of exploration drilling in the Beaufort Sea to bowhead whale migration corridors and/or subsistence activities makes it more likely that the Regional Supervisor would exercise authority requiring the capture of water-based muds and cuttings in the Beaufort Sea. The annual cost is estimated to include a capital cost of $13.0 million to install capture equipment. The annual cost of operating the equipment disposing of cuttings is estimated to be $16.5 million. The average annual cost of this provision is estimated to be $18.1 million.

Mudline Cellars (Formerly § 250.402)

One commenter stated the cost of complying with the requirements proposed at § 250.402(c) will result in a total cost of $4 billion over the ten years, compared to the Bureaus' estimated cost of $240 million. The commenter based its estimated costs on the assumptions in Exhibit 3 of the initial RIA, which assume 48 wells will be drilled during the ten-year period. The commenter estimated the cost per season for a two-rig program to be approximately $1.5 billion, leading to daily operating rig costs (based on a 100 day drilling season) of $7.5 million and lost rig day costs of $6 million. The commenter calculated that, based on the assumption of 1.5 days of additional lost time per well due to this provision, the cost is $9 million per well (1.5 days at a lost rig day rate of $6 million), which is three times larger than the initial RIA estimate of $2 million per well. The commenter argued that assuming a cost of $6 million per operating day results in an additional estimated cost of $9 million per well, and $432 million across the 48 wells assumed to be drilled in the ten-year period. The commenter further adds that inclusion of the costs for each rig to buy and maintain a dedicated mudline cellar bit adds $298 million to the cost across the 10-year program. Another commenter stated that the requirement for securing a well has long-required the use of well cellars and proper temporary abandonment of Arctic wells. The commenter asserted this is not a new requirement and should be included in the baseline costs.

BOEM and BSEE agree that the requirements under the former § 250.402 (finalized in the Well Control Rule as § 250.720), including mudline cellars, are a long-standing industry practice and are required by existing regulations (§ 250.738) for Arctic OCS MODU drilling operations in ice scour areas. Accordingly, we have included the costs of the mudline cellars in the final RIA's baseline cost estimate. BOEM and BSEE have adjusted the estimated compliance cost based on information received in comments and the number of drilling days required to drill or construct a mudline cellar. We assume that the mudline cellar will take 10 days to drill or construct, based on actual time required during the 2015 exploration drilling program. We further updated the average daily drilling cost. These calculations resulted in a mudline cellar drilling cost of approximately $37,000,000 per well.

The mudline cellar requirement imposes a capital cost per drilling rig (for the mudline well cellar drill bit) and a maintenance cost (for upkeep of the drill bit). These costs were not fully considered in the initial RIA but are included in the final RIA.

Real-Time Monitoring Requirements (§ 250.452)

One comment questioned the assumption of the initial RIA that there is an incremental cost of $6 million per year, per rig for RTM requirements. The comment suggests that, because these measures were employed by Shell in 2012, there is no incremental cost to that operator. BOEM and BSEE agree and consider RTM costs to be part of the regulatory baseline. RTM was required as part of the approvals for the 2012 and 2015 Shell EPs, and the use of RTM has become a standard practice by industry on the Arctic OCS. Additionally, RTM provisions are codified in the final BSEE BOP/Well Control rule at § 250.724. While RTM is considered a baseline cost, BOEM and BSEE acknowledge there may be instances when RTM could be required under § 250.452 but not under § 250.724. Section 250.724 requires RTM when conducting well operations with a subsea BOP, with a surface BOP on a floating facility, or when operating in an HPHT environment. Arctic exploratory drilling may be conducted from grounded platforms such as a jack-up rig that do not utilize a subsea BOP. In these cases RTM would be required and could be considered a compliance cost assigned to § 250.452. However, as a general matter, the use of real-time monitoring has become an industry standard in the context of challenging conditions such as deepwater or HPHT wells (as reflected in the Well Control Rule) and Arctic OCS exploratory drilling (as reflected here and in the 2012 and 2015 plans). Accordingly, based on the requirements of the Well Control Rule and standard industry practices in challenging Arctic conditions, BOEM and BSEE have concluded that costs associated with maintaining real-time monitoring capabilities are properly considered baseline costs.

One commenter suggests that the RTM compliance costs were underestimated. They suggest that the cost to operate a monitoring system is approximately $10,000 per day, compared to the $5,000 per day used in the initial RIA. They suggest that, in a 100-day season, the system would be operated for approximately 144 days, with 30 days prior to the season utilized to get systems up and running and then two weeks following the season to close down. They further suggest that the initial system would cost $400,000 per operator with an additional $200,000 every three years to replace or update monitoring system components.

In the baseline cost analysis, BOEM and BSEE assume the RTM systems would be operated for 126 days per year, which consists of the 82 day drilling season (116 days in the season less the 34 day shoulder season), 30 days for set-up, and 14 days for take-down. We have kept the $5,000 average daily cost consistent with information received as part of the BSEE Well Control Rule. The initial system cost and refurbishing cost were revised based on this comment. A $400,000 initial system cost and a $200,000 refurbishing cost, incurred every three years, are included in the baseline final RIA cost estimate.

APD Cost (§ 250.470)

One commenter expressed concern about the incorporation of API RP 2N Third Edition as part of an operators' APD submittal. The commenter mentions that the RP explicitly states its inapplicability to MODUs, and concludes that the Bureaus' attempt to estimate the cost of incorporating an inapplicable standard as required under this provision results in undefinable costs, given the variety of issues raised by such a requirement. The commenter estimated the increased average annual costs to be $9,818, which assumes 20 hours of industry staff time and 10 hours of BSEE staff time.

BOEM and BSEE have revised the cost assumptions in response to this comment. The final RIA assumes an industry mid-level engineer will spend 20 hours on the documentation associated with the provision, which results in an annual cost of $1,956 per rig. It is assumed a senior BSEE engineer will spend 10 hours reviewing submittals associated with the requirement, for a cost of $979 per rig. With these assumptions, the average annual cost of this provision is estimated to be $10,273.

Source Control and Containment Cost (§ 250.471)

Two commenters recommend that the initial RIA's cost estimates of $31 million per year for SCCE, including a capping stack, cap-and-flow system, and containment dome, should be included in the baseline because this equipment has been required for OCS operations since 2010, pursuant to NTL 2010–N10 and Shell's 2012 EP. One of the commenters requested that, if SCCE costs are considered new regulatory compliance costs, then the capital and operating costs for each piece of SCCE should be explained.

BOEM and BSEE disagree that the costs are part of the baseline and have explained the cost assumptions in greater detail in the final RIA. The SCCE capital cost, in addition to the costs of deployment and testing of this equipment, is a compliance cost of the rule because the requirement to maintain SCCE is being formally codified in the regulations. The SCCE costs are summarized in the final RIA and total $681.9 million over 10 years (3 percent discounting).

One commenter stated that the costs for the SCCE requirements are significantly underestimated and that they should be $315 million to $685 million higher, over the ten-year period, than the costs associated with the SCCE requirements as presented in the initial RIA. The commenter asserted that the initial RIA incorrectly assumed no cost associated with the existing SCCE system by only including the cost for the purchase of a second system in 2018. The existing system is the result of what the comment states are extra-regulatory conditional permit requirements, and as such the $270 million used in 2018 was also utilized in 2015 to recognize the cost already incurred by the industry. Furthermore, the commenter states that its experience indicates that BSEE has substantially underestimated the annual operating costs of the system, accounting for only $1.2 million in operating costs per year. The commenter argued that all costs evaluated in the initial RIA assumed a continued WCD of 25,000 barrels per day as used in the approved Shell Chukchi OSRP. The commenter stated that if prospects with larger estimated WCDs are evaluated, the costs for the development and operation of the SCCE systems will scale, at minimum, linearly from the costs that are currently included, and the commenter recommended this increased cost should be incorporated into the analysis. The commenter also asserted that the cost for an annual test or exercise of the system, which would involve a full deployment of the SCCE, is underrepresented in the initial RIA. The commenter suggests that, based on current costs and experience from a 2015 deployment test, an annual test would cost an estimated $5.9 million per year per system.

BOEM and BSEE have revised the cost estimates for the SCCE testing requirements based on information received in comments and adopted the central SCCE capital scenario from the initial RIA. The central SCCE scenario assumes that one company purchases SCCE for its own use and the other two operators share SCCE. The calculation of the volume of oil under a WCD scenario varies from site to site. This information is required as part of the OSRP for each facility under § 254.47. BOEM and BSEE do not include additional costs for revised SCCE in the event that larger WCD scenarios are developed for other prospects, as these costs would be too speculative to estimate at this time. The final RIA estimates the average annual deployment and testing cost to be $22,117,333.

Relief Rig Requirements (§ 250.472)

Two commenters recommend that the $0.55 billion relief rig costs should be removed from the incremental analysis and be included in the baseline because the Bureaus have previously imposed the requirement that Arctic OCS exploration operators have a relief rig. One of the commenters noted that the costs of the standby relief rigs should not be included because operators can plan simultaneous exploration operations using two or more drilling rigs where no drilling rig would be idle on stand-by. The commenter further noted that two or more operators drilling in the Arctic at the same time could agree to share relief rig services through a mutual aid agreement, whereby no drilling rig would be idle on stand-by. The commenter concludes there is no incremental cost for a stand-by relief rig in either case, because the rigs are actively drilling wells and included in the baseline economics, and would only be called up in an emergency to provide relief rig services.

BOEM and BSEE have continued to assign the compliance cost of the relief rig and shoulder season to the rule. However, the revised activity assumptions in the final RIA exclude the presence of an idle standby relief rig. Instead of an idle standby relief rig, it is assumed that the single operator in years 2 and 3 would operate two rigs and designate each rig as a relief rig for the other. Because the exploration activity scenario no longer includes an idle relief rig, no costs are associated with this provision. BOEM and BSEE maintain that the requirement that a relief well be drilled before seasonal ice encroachment is a compliance cost of the rule. The compliance cost for the shortening of the drilling season necessitated by these requirements is estimated to be $84.4 million per year in years 2 and 3 and $177.9 million per year in years 4 to 10.

One commenter suggests that BSEE's baseline economic modeling should be based on OCS lease operators being able to drill a single well per season per rig through 2017. The commenter further suggests the realization of a multiple-well drilling season for any single drilling unit is not likely, given the seasonal restrictions, requirement for a mud line cellar, and time required to drill a relief well.

BOEM and BSEE disagree that a multiple-well drilling season is not likely. However, we do agree, considering Shell's 2015 announcement, that the number of wells per season should be revised. Accordingly, beginning in year 2 we have revised the assumptions for the number of wells drilled per season to have a maximum of two wells per rig. The initial RIA assumed four wells for one rig in 2016, and the final RIA maintains the assumptions of four wells for two rigs in years 2 and 3 and six wells for 4 rigs from years 4 to 10. By assuming that two wells per season can be drilled, we are potentially assuming a higher level of activity and thus ensuring that we are not underestimating the costs of the regulation. We considered comments on the number of exploratory wells assumed in the analysis, and upon careful consideration have determined the scenario used in the final RIA reflects a reasonable estimate for the number of wells over the 10 year period to avoid underestimating the regulatory costs.

One commenter recommended any cost-benefit analysis of this rule package should account for the erosion to an operator's portfolio of lease holdings caused by lost drilling days resulting from the requirement for a same season relief well. The commenter asserted the regulations would make it difficult, and in many cases impossible, to complete one well in a single season and that the fewer days an operator has during the open-water season to explore its lease, the greater the number of its leases that will expire before they can be evaluated. The commenter points to the NPC Arctic Potential Study, where it is noted that the U.S. lease system is development based, and to retain a lease, the operator must have gained enough information to be able to move into the commercial development phase by the end of the 10-year primary term for an OCS lease. The short drilling season, it was argued, could make this determination practically impossible to achieve within the 10-year term when the drilling of several wells may be required to enable appraisal of a field.

BOEM and BSEE have reexamined, carefully considered and developed new estimates of the number of lost drilling days resulting from the requirements of the final rule, and have derived the effect of these lost drilling days in terms of their cost to operators. It is assumed that the relief rig requirement would shorten the drilling season by 34 days, out of the estimated 116 day drilling season. This 29 percent reduction in drilling days is used to estimate that 29 percent of the annual costs of the drilling rig is lost due to this provision. There are also savings realized during the 34 days from support vessels demobilizing earlier and other beneficial activities that can be pursued during that time, however these benefits were not incorporated into the cost estimates. The final RIA estimates the annual shoulder season costs as $84.42 million per year in years 2 and 3 and $177.95 million per year in years 4 to 10.

With regard to the NPC Arctic Potential Study, as discussed in Section IV.B.1. *General Comments,* BOEM and BSEE subject matter experts participated in the development of this study and have utilized, where appropriate, knowledge gained from its development. BOEM and BSEE recognize the NPC Arctic Potential Study as a valuable comprehensive study that considers the research and technology opportunities that exist for the prudent development of U.S. Arctic oil and gas resources. There are, however, a number of statements in the NPC Arctic Potential Study BOEM and BSEE found to be without support. For example, it suggested that there were currently available technologies, other than a relief well, that would kill and permanently plug an out-of-control well. BSEE and BOEM are aware of no such technology. In addition, the NPC Arctic Potential Study is only one of the resources that our regulatory experts considered in achieving our goal of developing regulations to ensure the safe and responsible development of petroleum resources on the Arctic OCS.

One commenter argued that the cost per year of a relief rig, and number of years for inclusion of the cost of the relief rig, is overestimated. The initial RIA utilized a methodology to calculate the cost of a relief rig that took the assumed day rate cost of a rig at $2 million per day and multiplied that by the number of days in a season at 138 days to arrive at a total of $276 million for a season. The commenter suggests that this methodology overstates the cost that would be associated with a rig that was being held on stand-by as a true relief rig at a location such as Dutch Harbor. The commenter cites an analysis performed by ENVIRON which estimated a cost of approximately $212 million per season based on publicly available data sources and the requirement of a rig, tugs to transport the rig, and a support vessel on stand-by (ENVIRON International Corporation. Arctic Regulations Benefit Cost Analysis. 2014. p. 9).

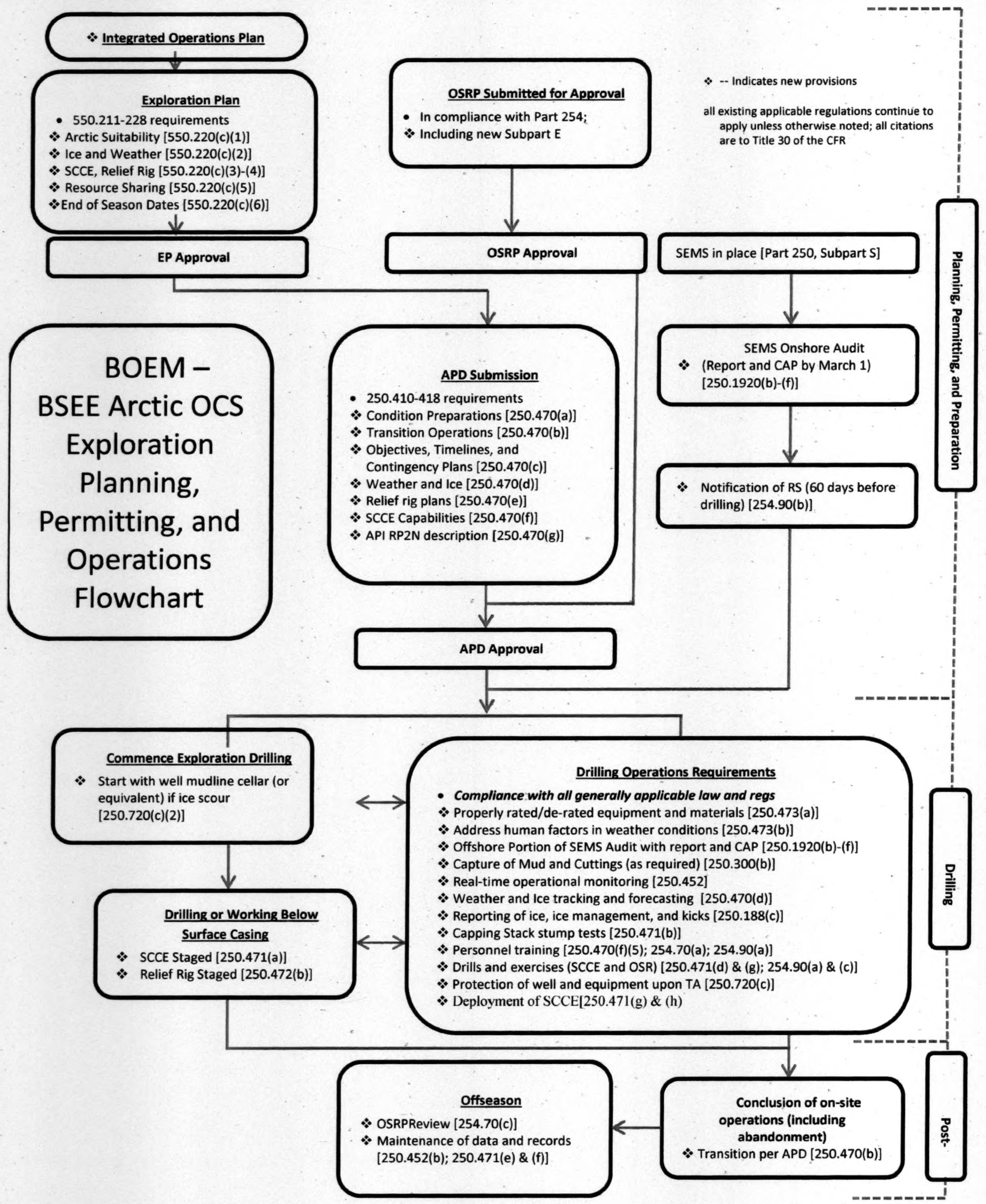
BOEM and BSEE considered comments on the relief rig requirements of the proposed rule. We have revised both the day rate cost for Arctic drilling rigs and revised the cost of the shoulder season as discussed above. The revised Arctic exploration scenario has assumed that all rigs are conducting exploratory drilling operations.

SEMS Auditing (§ 250.1920)

Two commenters question the auditing costs. One commenter is concerned that the cost estimated by BSEE for auditing services was underestimated by 50 percent. Another commenter thinks that the estimate of the incremental cost of the SEMS requirements was reasonable considering the scope of the requirement.

BSEE has recently updated its cost estimates for SEMS Audits and now estimates the average cost to audit a complex operation on the OCS at $250,000/audit cycle. BSEE believes that this incremental cost is more reasonable given the requirement that the audit provide an objective evaluation to test and contribute to continual improvements in the management system's ability to manage risk.

D. Arctic Exploratory Drilling Process Flowchart


❖ Integrated Operations Plan
Exploration Plan
• 550.211-228 requirements
❖ Arctic Suitability [550.220(c)(1)]
❖ Ice and Weather [550.220(c)(2)]
❖ SCCE, Relief Rig [550.220(c)(3)-(4)]
❖ Resource Sharing [550.220(c)(5)]
❖ End of Season Dates [550.220(c)(6)]
EP Approval
OSRP Submitted for Approval
• In compliance with Part 254;
❖ Including new Subpart E
OSRP Approval
❖ -- Indicates new provisions
all existing applicable regulations continue to apply unless otherwise noted; all citations are to Title 30 of the CFR
SEMS in place [Part 250, Subpart S]
SEMS Onshore Audit
❖ (Report and CAP by March 1) [250.1920(b)-(f)]
❖ Notification of RS (60 days before drilling) [254.90(b)]
Planning, Permitting, and Preparation
BOEM – BSEE Arctic OCS Exploration Planning, Permitting, and Operations Flowchart
APD Submission
• 250.410-418 requirements
❖ Condition Preparations [250.470(a)]
❖ Transition Operations [250.470(b)]
❖ Objectives, Timelines, and Contingency Plans [250.470(c)]
❖ Weather and Ice [250.470(d)]
❖ Relief rig plans [250.470(e)]
❖ SCCE Capabilities [250.470(f)]
❖ API RP2N description [250.470(g)]
APD Approval
Commence Exploration Drilling
❖ Start with well mudline cellar (or equivalent) if ice scour [250.720(c)(2)]
Drilling or Working Below Surface Casing
❖ SCCE Staged [250.471(a)]
❖ Relief Rig Staged [250.472(b)]
Drilling Operations Requirements
• Compliance with all generally applicable law and regs
❖ Properly rated/de-rated equipment and materials [250.473(a)]
❖ Address human factors in weather conditions [250.473(b)]
❖ Offshore Portion of SEMS Audit with report and CAP [250.1920(b)-(f)]
❖ Capture of Mud and Cuttings (as required) [250.300(b)]
❖ Real-time operational monitoring [250.452]
❖ Weather and Ice tracking and forecasting [250.470(d)]
❖ Reporting of ice, ice management, and kicks [250.188(c)]
❖ Capping Stack stump tests [250.471(b)]
❖ Personnel training [250.470(f)(5); 254.70(a); 254.90(a)]
❖ Drills and exercises (SCCE and OSR) [250.471(d) & (g); 254.90(a) & (c)]
❖ Protection of well and equipment upon TA [250.720(c)]
❖ Deployment of SCCE[250.471(g) & (h)
Drilling
Offseason
❖ OSRPReview [254.70(c)]
❖ Maintenance of data and records [250.452(b); 250.471(e) & (f)]
Conclusion of on-site operations (including abandonment)
❖ Transition per APD [250.470(b)]
Post-

E. Conclusion

The final rule establishes, through both performance-based and prescriptive requirements, what will be required of operators seeking to conduct exploratory drilling operations on the Arctic OCS. The requirements contained in the final rule reflect the unpredictable and challenging nature of exploratory drilling operations in the Arctic. The regulations require early and comprehensive planning of operations, particularly with respect to safety systems and emergency response vessels and equipment. These regulations seek to ensure that operations are undertaken in a safe and environmentally responsible manner.

V. Procedural Matters

A. Regulatory Planning and Review (E.O. 12866 and E.O. 13563)

Changes to Federal regulations must undergo several types of economic analyses. First, E.O. 12866 and E.O. 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select a regulatory approach that maximizes net benefits (accounting for the potential economic, environmental, public health, and safety effects). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. Under E.O. 12866, an agency must determine whether a regulatory action is significant and, thus, subject to the requirements of the E.O. and OMB review. Section 3(f) of E.O. 12866 defines a "significant regulatory action" as any rule that:

1. Has an annual effect on the economy of $100 million or more, or adversely affects in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities (also referred to as "economically significant");
2. Creates serious inconsistency or otherwise interferes with an action taken or planned by another agency;
3. Materially alters the budgetary impacts of entitlement grants, user fees, loan programs, or the rights and obligations of recipients thereof; or
4. Raises novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in E.O. 12866.

B. E.O. 12866

E.O. 12866 provides that OMB's OIRA will review all significant rules. Pursuant to the procedures established to implement section 6 of E.O. 12866, OMB has determined that this final rule is significant because it may have an effect on the economy of $100 million. The legal and policy issues identified by OMB are the requirements for SCCE, relief rig availability, and the shoulder season to reflect current conditions for Arctic OCS exploration plan and permit approval. The following discussion summarizes the economic analysis. The complete final RIA can be found in the regulatory docket for this final rule at *www.regulations.gov* (BSEE–2013–0011).

Before authorizing the exploration for Arctic OCS hydrocarbon resources, BOEM and BSEE must ensure that exploration can occur safely and with minimal environmental risk. This final rule provides a regulatory framework specifically designed for Arctic exploration and outlines the specific requirements for exploratory activities. Its purpose is to provide the requirements and standards to which all individual operations will be held.

The available Arctic OCS oil spill control and response capabilities have been strengthened at considerable cost over the last few years. The incremental compliance costs for new provisions required in this rulemaking are on top of measures already taken by industry. Two of the requirements of this regulation are considered baseline, that is, not new costs, as they reflect current industry practice under current regulations. At the same time, for informational purposes, we have accounted for this cost to industry of existing baseline requirements for exploratory operations in the Arctic that are being included in this rulemaking. The final RIA includes estimates of both new regulatory compliance costs and costs associated with the baseline.

While a catastrophic oil spill resulting from exploratory drilling on the Arctic OCS is highly unlikely due to the nature of the geology, the shallow water depth, and the relative simplicity of well construction for wells likely to be drilled in the Arctic OCS, because the potential adverse effects of a catastrophic oil spill would be severe, steps must be taken to reduce the risk of a spill risk and its duration should one occur. The American public greatly values the Arctic. It is viewed as a pristine, unspoiled environment. With this in mind, a catastrophic oil spill would have severe impacts (at least on a meaningful human time scale). BOEM and BSEE have determined that the benefits of this rule exceed the costs when qualitative factors are considered and reflect society's strong risk averse preference in the Arctic.

Economic Analysis

1.1 Compliance Costs

The provisions of the final rule are estimated to result in compliance costs of $2.0 billion under 3-percent discounting and $1.7 billion under 7-percent discounting over 10 years. The baseline provisions are estimated to cost $1.8 billion under 3-percent discounting and $1.5 billion under 7-percent discounting over 10 years.

Table 1 shows the final rule's provisions and primary benefit. We have included the estimated costs for reference. As the table emphasizes, the key provisions of this rule are specifically intended to minimize the risks of catastrophic oil spills and minimize the damage of a spill, should one occur.

TABLE 1—REGULATORY PROVISIONS, COSTS AND BENEFITS

Provision	Rule cost (discounted at 3% over 11 years, $ millions)	Baseline cost (discounted at 3% over 11 years, $ millions)	Primary benefit
(a) Additional Incident Reporting Requirements	$0.56		Improves information to Federal agencies.
(b) Additional Pollution Prevention Requirements	141.09		Minimizes natural resource impacts.
(c) Additional Requirements for Securing Wells *		$1,811.912	Reduces risk of a spill.
(d) Real-time Monitoring Requirements **		14.101	Reduces risk of a spill.
(e) Additional Information Requirements for APDs	0.23		Improves information to Federal agencies.
(f) Incorporation of API RP 2N	0.08		Reduces risk of a spill.
(g) Additional SCCE Requirements	681.92		Improves control and containment of a spill.
(h) Relief Rig Requirements †	1,206.55		Improves control of a spill.
(i) Additional Auditing Requirements	5.58		Improves information to Federal agencies.
(j) Real-time Location Tracking Requirements	0.96		Improves information to Federal agencies.
(k) IOP Requirements	7.67		Improves coordination among Federal agencies.
(l) Planning Information Requirements to Accompany EPs.	2.57		Improves information to Federal agencies.

TABLE 1—REGULATORY PROVISIONS, COSTS AND BENEFITS—Continued

Provision	Rule cost (discounted at 3% over 11 years, $ millions)	Baseline cost (discounted at 3% over 11 years, $ millions)	Primary benefit
(m) Industry Familiarization with the New Rule	0.37	....	General.
Total	2,047.60	1,826.012	

* The drilling of mudline cellars has been a longstanding practice in the Chukchi and Beaufort Seas extending back to the 1980's; thus this provision is assigned to the regulatory baseline.

** The cost for this provision is assigned to the regulatory baseline. The BSEE BOP/Well Control rule at § 250.724 requires real-time monitoring for all operations with a subsea BOP or surface BOP on a floating facility.

† Provision (h) includes the baseline compliance cost attributable to the amount of time that an operator will "lose" from the open water season as a result of the relief rig/shoulder season requirement. A 116 day Arctic drilling season is estimated to be shortened by 34 days (29%).

1.2 Benefits

BOEM and BSEE have concluded that these exploratory drilling regulations will provide regulatory clarity and certainty, resulting in a more comprehensive Arctic OCS oil and gas regulatory framework. The provisions in this rule codify existing requirements in the Arctic designed to reduce the probability of a catastrophic spill, reduce the impacts of a spill should one occur, improve the coordination of operations among Federal agencies, and minimize natural resource and ecosystem impacts of offshore operations in the Arctic.

Due to both the uncertainty and difficulty of measuring benefits, we do not offer an aggregate quantitative assessment of all of the final rule's provisions. Instead, we present a combination of quantitative and qualitative discussions based on the benefits of the different provisions of this rule. In general, the individual provisions of this rule serve four main beneficial purposes: (1) Improving information to and coordination among Federal agencies regarding Arctic operations, (2) minimizing natural resource impacts, (3) reducing the risk of oil spills, including a catastrophic oil spill, and (4) improving containment and reducing severity of a catastrophic oil spill. Each of these benefits is discussed in more detail in the final RIA. In addition to these four main benefits, in aggregate the rule provides regulatory certainty to industry and the assurance to stakeholders and partners that DOI is committed to safe Arctic operations.

1.2.1 Benefit: Improving Information to, and Coordination Among Federal Agencies

The final rule includes new provisions that require additional information sharing and availability. Because the nature of this benefit is difficult to quantify, it is considered qualitatively. The costs of the applicable provisions total $17.6 million and comprise 0.9 percent of the compliance costs assigned to the rule. They are designed to achieve better coordination among BSEE, BOEM, and other Federal agencies. For example, § 550.204 requires operators to provide information which will facilitate interagency coordination between DOI and other relevant Federal agencies, as recommended in the DOI *Report to the Secretary of the Interior, Review of Shell's 2012 Alaska Offshore Oil and Gas Exploration Program.*[47] The benefits of this information sharing allow different Federal agencies to manage potential conflicts and ensure compliance with environmental and regulatory standards. The necessity of coordination and information sharing between Federal agencies is documented in E.O. 13580, which created the Interagency Working Group on Coordination of Domestic Energy Development and Permitting in Alaska.[48] This E.O. recognizes the importance of interagency coordination for "safe, responsible, and efficient development of oil and natural gas resources in Alaska . . . while protecting human health and the environment as well as indigenous populations." This rule provides assurance to other Federal agencies that BOEM and BSEE are protecting the region and are fostering communication and collaboration with government partners.

1.2.2 Benefit: Minimizing Natural Resource and Subsistence Impacts

The additional pollution prevention requirements in paragraphs (b)(1) and (2) of § 250.300 constitute 6.9 percent of the rule's estimated compliance cost. The revised pollution prevention requirements that are responsible for these incremental compliance costs clarify the Regional Supervisor's discretionary authority to ensure that operators capture all water-based muds and associated cuttings from Arctic OCS exploratory drilling operations following completion of the conductor casing to prevent discharge of these water based muds and associated cuttings into the marine environment. The Regional Supervisor would be more likely to exercise authority requiring the capture of water-based muds and cuttings in the Beaufort Sea, as that is the area where whales migrate through subsistence harvest areas. Given the difficulty of calculating how the discharge of muds and cuttings could affect marine mammals, their habitat, and subsistence activities, we have not quantified the benefits of these provisions. However, we recognize the importance of subsistence harvests in the region and conclude these provisions are necessary to preserve a food source and cultural tradition.

1.2.3 Benefit: Reducing the Risk of a Catastrophic Oil Spill

Both the provision for RTM and the additional requirements for securing wells help reduce the risk of a catastrophic oil spill from Arctic OCS exploration activities. These baseline provisions are designed to reduce the risk of such an oil spill occurring.

A catastrophic oil spill is characterized as a "low-probability, high-consequence" event because it is infrequent but has large consequences when it does occur. Previous frequency/probability studies of oil spills resulting from loss of well control have estimated catastrophic oil spill risk, but also have emphasized the extreme difficulty in estimating the probability that an event will actually occur, in part because the number of such large accidents offshore is small. Even more difficult is determining the reduction in the probability of occurrence that a new regulation would actually achieve. Given the nature of the new requirement being imposed on industry as a result of this provision (*i.e.*, additional documentation that the recommended practice was followed), we have not quantified the effect of this provision on the reduction in risk or the estimated avoided spill costs associated with the provision. The benefits of the final rule's baseline provisions are discussed in the final RIA.

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[47] *http://www.doi.gov/news/pressreleases/upload/Shell-report-3-8-13-Final.pdf.*

[48] *https://www.whitehouse.gov/the-press-office/2011/07/12/executive-order-13580-interagency-working-group-coordination-domestic-en.*

1.2.4 Benefit: Reducing the Duration of Catastrophic Oil Spills

Provisions of this final rule are designed to ensure that equipment and personnel are readily available to respond to a loss of well control event. As shown in Table 1 in the RIA, the most costly provisions are designed to reduce the duration of a loss of well control event should one occur. To compare the benefit of reducing the duration or severity of a catastrophic oil spill with the costs incurred, the final RIA conducts analyses on the specific provisions of the rule designed to reduce spill duration or severity. Section 250.471 of the final rule requires additional SCCE testing and documentation, which can reduce the impact of a catastrophic oil spill should one occur. Section 250.472 requires Arctic OCS operators to have access to a separate relief rig that would be available if a loss of well control was to occur and drilling a relief well became necessary. The rule requires a drilling rig be located such that it could arrive on location, drill a relief well, kill and abandon the original well, and abandon the relief well prior to expected ice encroachment at the drill site, but no later than 45 days after a loss of well control. The SCCE and relief rig requirements make up 92 percent of the rule's compliance cost.

The SCCE testing requirements can help reduce the duration of catastrophic oil spills in two ways. First, through regular tests of the SCCE, crew members gain practice and experience in deploying the equipment which could ultimately lead to faster and more efficient deployment should an oil spill occur. Second, through these regular tests crew members can identify faulty equipment. This allows problems to be corrected before the equipment is actually needed.

Given the difficulties associated with quantifying the exact influence this provision could have on reducing the severity of an oil spill, we conducted an analysis of the SCCE testing requirements. The final RIA includes calculations for the smallest reduction in oil spill duration, due to the SCCE testing requirements, necessary for this provision of the rule to be cost-beneficial. Also included in the final RIA is a risk analysis that considers the historical frequency of catastrophic OCS oil spills.

1.2.5 Benefit: Regulatory Certainty to Industry

The regulatory baseline includes recent Arctic OCS exploration best practices and regulatory requirements that are being clarified and codified in this rule. Therefore, a benefit of this final rule is to provide the regulatory certainty of what is required for operators to safely explore for hydrocarbons on the Arctic OCS.

The oil and gas industry requires regulatory stability to undertake timely and efficient exploration. With this rule, the oil and gas industry can more effectively plan and conduct exploratory drilling on the Arctic OCS with lower risk and fewer delays than under the existing rules and clarifying NTLs. According to BOEM's 2016 Assessment of Undiscovered Technically Recoverable Oil and Gas Resources of the Nation's Outer Continental Shelf, there are approximately 23.6 billion barrels of technically recoverable oil and about 104.4 trillion cubic feet of technically recoverable natural gas in the Beaufort Sea and Chukchi Sea Planning Areas combined. The NPC Arctic Potential Study listed as one of its key findings that the "economic viability of U.S. Arctic development is challenged by operating conditions and the need for updated regulations that reflect arctic conditions" (p. 10). This rule provides those Arctic-specific regulatory requirements.

1.2.6 Benefit: Assurance to Stakeholders and Partners

In addition to providing regulatory certainty to industry, another benefit of this rule is to provide assurance to stakeholders, partners, Tribes, citizens, and other countries that the U.S. will explore the Arctic safely and with appropriate environmental stewardship. This rule builds on one of the themes from the NPC Arctic Potential Study that steps must be taken to "secure public confidence" that activities can be conducted safely. This rule helps achieve the National Arctic Strategy goals of protecting the unique and sensitive Arctic ecosystems and the subsistence needs, culture, and traditions of the Alaska Native communities.

The U.S. Arctic Policy recognizes the interconnectedness of Arctic nations and commits to coordinating with other Arctic nations to ensure operationally safe and environmentally sustainable development. The U.S. is a Party to the Agreement on Cooperation on Marine Oil Pollution Preparedness and Response in the Arctic and must comply with the Agreement, including the provisions in Article 4: Systems for Oil Pollution Preparedness and Response. These regulations help provide assurances to the international community that our operators in the Arctic will follow the appropriate preparedness procedures and do everything possible to prevent an oil spill, or minimize the effects should one occur. Further, the NPC Arctic Potential Study cites the importance of the U.S. national Arctic strategy in promoting Arctic activities because of their interaction with national security, foreign policy, and energy policy. The goal of the Arctic strategy is to "seek an Arctic region that is stable and free of conflict, where nations act responsibly in a spirit of trust and cooperation, and where economic and energy resources are developed in a sustainable manner that respects the fragile environment and the interests and cultures of indigenous peoples." [49]

C. E.O. 13563

E.O. 13563 reaffirms the principles of E.O. 12866 while calling for improvements in the Nation's regulatory system to promote predictability, to reduce uncertainty, and to use the best, most innovative, and least burdensome tools for achieving regulatory ends. In addition, E.O. 13563 directs agencies to consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public where these approaches are relevant, feasible, and consistent with regulatory objectives. It also emphasizes that regulations must be based on the best available science and that the rulemaking process must allow for public participation and an open exchange of ideas. We developed this final rule in a manner consistent with these requirements. BOEM and BSEE worked closely with engineers and technical staff to ensure this rulemaking follows sound engineering principles through research, standards development, and interaction with industry.

E.O. 13563 requires an analysis of employment impacts. BOEM and BSEE considered whether the regulation might adversely affect Alaska employment by reducing the potential for jobs associated with the offshore oil and gas industry. The Arctic region of Alaska has not relied previously on Federal offshore oil production for economic development, but any eventual production would be a positive contribution to the State's and the Nation's economic development. Although BOEM and BSEE, when considering the cumulative impacts of Arctic specific provisions in this rule, acknowledge reduced employment might occur, the safety and environmental protections are necessary to protect our fragile Arctic natural resources.

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[49] NPC Arctic Potential Study, Executive Summary, p. 9 (March 2015).

Conversely, the final rule brings potential benefits to the local economy and cultural traditions from reduced risk of spills. A catastrophic spill would have negative economic impacts far beyond the offshore oil and gas industry. A catastrophic spill could disrupt subsistence whaling on which Native Alaskans rely for food and for their cultural preservation. Thus, assessing the net cost or benefit of the rule to the local economy is not practical, given the number of factors involved and the level of uncertainty that surrounds each of them.

E.O. 13563 encourages agencies to consider the cumulative cost of regulations. Consistent with E.O. 13563 and OMB guidance in the March 20, 2012, memorandum from the Administrator for the OIRA, the final RIA has made an effort to "take account of the cumulative effects of new and existing rules." Thus, the RIA appendix accounts for the significant regulatory baseline costs codified in this rulemaking.

D. Regulatory Flexibility Act

For the reasons explained in this section, BOEM and BSEE have concluded this rule will not have a significant economic impact on a substantial number of small entities and, therefore, a final regulatory flexibility analysis is not required.

BOEM and BSEE prepared an Initial Regulatory Flexibility Analysis (IRFA) for the proposed rule to assess the impact of the proposed rule on small entities, as defined by the applicable Small Business Administration size standards. The IRFA was prepared using conservative assumptions and sought public comments on potential small entity impacts. No comments on the potential impact to small entities were received during the proposed rule comment period. Based on the profile of current Arctic lessees, no small companies hold leases on the Arctic OCS. Previously only one small company holding only one lease held acreage in the Arctic. This company relinquished its lease in March 2016. Considering the past and current Arctic lease holding profiles and the challenges of operating in the Arctic, we certify that this final rule will not have a significant economic impact on a substantial number of small entities.

The final rule affects operators and Federal oil and gas lessees that could conduct exploratory drilling on the Arctic OCS. The Regulatory Flexibility Act, 5 U.S.C. 601–612, defines small entities as small businesses, small nonprofits, and small governmental jurisdictions. We have identified no small nonprofits or small governmental jurisdictions that the rule would impact. Businesses subject to this rule fall under North American Industry Classification System (NAICS) codes 211111 (Crude Petroleum and Natural Gas Extraction) and 213111 (Drilling Oil and Gas Wells). For these classifications, a small business is defined as one with fewer than 1,250 employees (NAICS code 211111) and fewer than 1,000 employees (NAICS code 213111), respectively. A small entity is one that is "independently owned and operated and which is not dominant in its field of operation."

Consistent with the exploratory scenario for the final RIA analysis, BOEM and BSEE anticipate three businesses to conduct exploratory drilling on the Arctic OCS over the 10 years of analysis. Although any business holding a lease could conduct exploratory drilling on the Arctic OCS if it can meet the relevant BOEM and BSEE regulatory requirements, a viable Arctic exploratory drilling program requires large geologic prospects and sufficient acreage to identify multiple drilling locations to support the prospect of economically viable development. Even absent this rulemaking, a single season of Arctic OCS exploratory drilling is estimated to cost approximately $1.5 billion and may only result in one or two exploratory wells being drilled.

According to BOEM's May 2016 list of Arctic OCS leaseholders, six businesses currently hold lease interests on the Arctic OCS. This rule directly affects all six Arctic lessees. Based on the small entity criterion, none of the six businesses is considered a small entity. From inception, to execution, to completion, every phase of Arctic OCS operations comes with inherent challenges and operational risks. The inherent challenges, including prospect and operational risks, and the attendant costs, make it exceedingly unlikely that any small entity will choose to conduct exploratory drilling operations on the Arctic OCS over the next decade.

Consistent with the existing and inherent costs and challenges associated with Arctic OCS exploratory drilling, the absence of interested and capitalized small entity lessees, and the 10-year scenario in which only three operators engage in Arctic OCS exploratory drilling, BOEM and BSEE certify that this rule will not have a significant economic impact on a substantial number of small entities.

E. Unfunded Mandates Reform Act of 1995 (UMRA)

This final rule will not impose an unfunded Federal mandate on State, local, or Tribal governments. This rule will require expenditures exceeding $100 million in a single year by offshore oil and gas exploration companies operating on the Arctic OCS. DOI has prepared written statements satisfying the applicable requirements of the UMRA, 2 U.S.C. 1501 *et seq.* Those requirements are addressed in the RIA and in the final rule itself.

Among other things, the final rule and the final RIA:

1. Identify the provisions of Federal law (OCSLA, CWA, and OPA) under which this rule is being finalized;
2. Include a quantitative assessment of the anticipated costs to the private sector (*i.e.,* expenditures on labor and equipment) of the final rule; and
3. Include qualitative and quantitative assessments of the anticipated benefits of the final rule.

Since all of the anticipated expenditures by the private sector analyzed in the RIA would be borne by the OCS oil and gas exploration industry in the Arctic region, the RIA analyses satisfy the UMRA requirement to estimate any disproportionate budgetary effects of the final rule on a particular segment of the private sector (*i.e.,* the offshore oil and gas industry).

As discussed in the Regulatory Planning and Review section of this final rule, and explained in the RIA, BOEM and BSEE considered two major regulatory alternatives for dealing with the safety and environmental concerns raised by exploration activities on the Arctic OCS. BOEM and BSEE have decided to move forward with this final rule, in lieu of the other alternative of taking no regulatory action, because the other alternative would not as efficiently or effectively address the safety, environmental or sociocultural concerns raised by various stakeholders and partners on the Arctic OCS or achieve the objectives of this final rule.

BOEM and BSEE have determined that the final rule would not impose any unfunded mandates or any other requirements on State, local or Tribal governments; thus, the final rule would not have disproportionate budgetary effects on such governments. Assuming, however, that the final rule might result in budgetary effects on the Arctic region, BOEM and BSEE have determined that it is not practical to accurately estimate such effects. Since the final rule would not impose any requirements on any entities, other than upstream oil and gas companies and their contractors engaged in Arctic OCS exploration activities, any budgetary effects in that area would be at least indirect, secondary results of actions or decisions taken by regulated (or unregulated) entities, based on a variety of circumstances (such as the price of oil, each entity's overall financial health, and the prospects of success of any exploratory drilling). Because each of those factors is variable and unpredictable, it is not practical to estimate how those factors might affect an entity's future decisions, or what indirect impacts, if any, such decisions could have on future regional budgets.

Similarly, BOEM and BSEE have determined that it is not reasonably feasible to accurately estimate the potential effects, if any, of the final rule on the National economy (*e.g.,* productivity, economic growth, employment, international competitiveness). The final rule would only affect exploratory drilling activities on the Arctic OCS, and any potential impact on the national economy would depend on the economics of any hydrocarbon discoveries and individual business decisions made by regulated entities (*e.g.,* whether or not to hire new employees). Moreover, any such decisions would likely be either local or regional in effect and unlikely to have any significant national economic impacts.

F. Takings Implication Assessment

Under the criteria in E.O. 12630, this final rule will not have significant takings implications. The final rule is not a governmental action capable of interference with constitutionally protected property rights. A Takings Implication Assessment is not required.

G. Federalism (E.O. 13132)

Under the criteria in E.O. 13132, this final rule will not have federalism implications. This final rule will not substantially and directly affect the relationship between the Federal and State governments. To the extent that State and local governments have a role in OCS activities, this final rule will not affect that role. A Federalism Assessment is not required.

H. Civil Justice Reform (E.O. 12988)

This final rule complies with the requirements of E.O. 12988. Specifically, this rule:

1. Meets the criteria of section 3(a) requiring that all regulations be reviewed to eliminate errors and ambiguity and be written to minimize litigation; and
2. Meets the criteria of section 3(b)(2) requiring that all regulations be written in clear language and contain clear legal standards.

I. Consultation With Indian Tribes (E.O. 13175)

Under the criteria in E.O. 13175, Consultation and Coordination with Indian Tribal Governments (dated November 6, 2000), DOI's Policy on Consultation with Indian Tribes (Secretarial Order 3317, Amendment 2, dated December 31, 2013), the Alaska Native Corporation Consultation Policy (dated August 12, 2012), and Departmental Manual Part 512 Chapters 4 and 5 (dated December 2, 2014), we evaluated and determined that the subject matter of this rulemaking will have implications for federally recognized Tribes and ANCSA Corporations. As described earlier, future Arctic OCS exploratory drilling activities conducted pursuant to this final rule could affect Alaska Natives, particularly their ability to engage in subsistence and cultural activities.

BOEM and BSEE are committed to regular and meaningful consultation and collaboration with Tribes on policy decisions that have Tribal implications including, as an initial step, through complete and consistent implementation of E.O. 13175, together with related orders, directives, and guidance. Therefore, BOEM and BSEE, in coordination with the Office of the Secretary of the Interior's Senior Alaska Representative, engaged in listening sessions, Government-to-Government Tribal consultations, and Government-to-ANCSA Corporations consultations to discuss the subject matter of the final rule and solicit input in the development of the final rule at several stages of the rule development process, from the earliest phases through the final rule development.

In the early stages of developing the NPRM, Government-to-Government consultation was held in Barrow between BOEM, BSEE, and the Inupiat Community of the Arctic Slope (ICAS), to both provide background to, and obtain information from, ICAS tribal leaders and council members. The following day, June 7, 2013, BOEM and BSEE met with leaders and council members of the Native Village of Barrow Inupiat Traditional Government in a separate Government-to-Government consultation. All Tribal input provided during the meetings was subsequently provided to DOI in writing and has been included in the decision record for this final rule.

BOEM and BSEE also held public listening sessions in South-central Alaska (Anchorage) and on the North Slope (Barrow) on June 6 and 7, 2013. The BOEM Alaska Region notified federally recognized Alaska Native Tribes and ANCSA Corporations of the June 6 and 7, 2013, public listening sessions and Government-to-Government consultations through phone calls, emails, newspaper announcements, and BOEM's Web site.

A series of follow-on meetings and listening sessions were held June 17–20, 2013, in Anchorage resulting, in part, in Government-to-Government consultation between BOEM, BSEE, and the Native Village of Nuiqsut and Government-to-ANCSA Corporation consultations between BOEM, BSEE, and the NANA Regional Corporation and the Cully Corporation (Point Lay ANCSA Corporation).

DOI continued consultation with affected federally recognized tribes and ANCSA Corporations following publication of the NPRM. On March 12, 2015, BOEM and BSEE held a public meeting in Barrow and met individually with leaders and council members of the Native Village of Barrow Inupiat Traditional Government, the AEWC and ICAS. The Bureaus also met with federally recognized Tribal leaders for six Government-to-Government consultations on the proposed regulations between April 20 and 24, 2015. The consultations were held in the following Alaskan locations: Kotzebue, Point Hope, Barrow, and Wainwright. During that week, consultations were held with the Native Village of Kotzebue, Native Village of Point Hope, ICAS, Native Village of Barrow, and Village of Wainwright. We also met with the president of the AEWC. On July 9, 2015, an additional Government-to-Government consultation was conducted with the Native Village of Nuiqsut by telephone conference.

Alaska Native Tribes' and ANCSA Corporations' comments on the proposed regulations, both written and oral, and the Bureaus' responses are summarized in this preamble (see Section IV *Section-By-Section Discussion of Changes and Comments*). ANCSA corporations primarily supported more performance-based regulations and recommended the proposed rule be withdrawn. Conversely, Alaska Native Tribes primarily supported the proposed regulations and recommended strengthening the provisions. Both written and oral comments received during Government-to-Government and Government-to-ANCSA Corporation consultations emphasized the importance of safe drilling operations. Discussions were primarily focused on impacts to, and protection of, subsistence hunting and fishing areas and species, including consideration of mammal and fish migratory patterns, hunting and fishing seasons, and impacts of pollutants and equipment movements. Concerns also included the relative lack of infrastructure, such as roads, housing, and equipment in coastal communities near proposed Arctic OCS oil and gas exploration areas, and inclusion of local Alaska Natives in monitoring and other activities. Commenters also requested that we incorporate traditional knowledge of the Arctic OCS into our decision-making for regulations. As discussed in Section IV, BOEM and BSEE have considered Alaska Native Tribes' and ANCSA Corporations' comments and incorporated them in the final rule as appropriate. For example, Alaska Native Tribes expressed concern over drilling mud and cuttings from exploratory activities adversely affecting marine species and impacting subsistence hunting. As a result, BSEE is requiring the capture of all petroleum-based mud and associated cuttings from Arctic OCS exploratory drilling operations. Capturing of water based mud and cuttings could also be required based on proximity to subsistence hunting, fishing locations, and potential effects on marine mammals and birds.

Only one commenter, the Cully Corporation, submitted a written comment asserting the Bureaus did not comply with the requirement to consult on this rulemaking.

Both BOEM and BSEE have sought and maintained an active relationship with the Cully Corporation. With respect to Cully Corporation's statement that neither Bureau consulted with them, it is important to note that both Bureaus did make an effort to reach out to Cully Corporation regarding this particular matter. We met with the Cully Corporation several times prior to the publication of the NPRM, including a Government-to-ANCSA Corporation consultation in June 2013. Another Government-to-ANCSA Corporation consultation was scheduled with Cully Corporation on April 21, 2015. We welcome the opportunity to discuss the Cully Corporation's concerns regarding implementation of this final rule, and thank them for the thoughtful and comprehensive written comments submitted on the proposed regulations.

J. E.O. 12898—Environmental Justice

E.O. 12898 requires Federal agencies to make achieving environmental justice part of their mission by identifying and addressing disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority and low-income populations. DOI has determined that this final rule does not have a disproportionately high or adverse human health or environmental effect on native, minority, or low-income communities because its provisions are designed to increase environmental protection and minimize any impact of exploration drilling on subsistence activities and Alaska Native community resources and infrastructure.

K. Paperwork Reduction Act (PRA)

This rule contains information collection (IC) requirements for both BOEM and BSEE regulations. Therefore, an IC request for each Bureau was submitted to OMB for review and approval under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et. seq.*); see each individual bureau's section for the OMB Control number, expiration date, and relevant information. The Paperwork Reduction Act (PRA) provides that an agency may not conduct or sponsor, and you are not required to respond to, a collection of information unless it displays a currently valid OMB control number. The public may submit comments at any time on the IC burden in this rule to either DOI/BOEM: ATTN: Office of Policy, Regulation and Analysis; OPRAVAM–BOEM–DIR or DOI/BSEE; ATTN: Regulations and Standards Branch; VAE–ORP; 45600 Woodland Road, Sterling, VA 20166.

As part of our continuing effort to reduce paperwork and respondent burdens, BOEM and BSEE invited the public to comment on any aspect of the reporting and recordkeeping burdens. We received 1,311 comments on this rulemaking. Three comments pertained to the information collection for BOEM and BSEE.

Commenters generally criticized the IOP provision as being duplicative or redundant of existing requirements. BOEM disagrees. The IOP rules are neither redundant nor duplicative of existing requirements. The IOP is meant to be an overview of all phases of the operator's proposed operations in order to allow the Federal agencies an earlier review in the planning process than currently exists. Moreover, the operator's IOP will contain planning information with less specificity than that furnished with the EP; as well as, the IOP will not require approval where the EP does require approval.

One of the commenters estimates that it will require 3,500 hours of industry staff time. We agree with the commenter that 90 hours for an IOP is low. However, we disagree with the commenter's recommendation to revise to 3,500 hours. BOEM anticipates that much of the conceptual planning information would already have been created by an operator planning to conduct exploration in the Arctic, and an IOP can be furnished through the operator's existing internal planning processes necessary for the preparation of Arctic operations. BOEM uses a conservative estimate derived from comments submitted by industry and direct experience reviewing a company's previously submitted IOP. During the IOP review period, BOEM can provide input to the operator, as well as request information from the operator regarding potential issues presented by the proposed activities concerning future plan approvals and permitting requirements. The estimated time it would take for the operator to provide any requested information to BOEM during the IOP review period is included in its burden hours estimate.

Therefore, based on comments received, changes to BOEM's hour burdens are as follows:

§ 550.204 submit all Arctic specific information required with IOP (+2,700).

§ 550.220 submit all Arctic specific information required with EP (+960).

Another comment received discussed duplicative information being submitted with the EP and the APD. BSEE and BOEM disagree with the duplication of information because the EP is intended to provide the operator the opportunity to present its overall plan for operations, and the APD is the technical document that provides the operator the opportunity to present details regarding how the plan will be implemented.

The commenter also discussed the burden hours being low, for example, the submission of detailed descriptions of environmental, meteorologic, and oceanic conditions expected at well site(s); etc. BSEE agrees and has increased two of the hour burdens associated with certain requirements. The changes are as follows:

§ 250.470(a); 417; 418—NEW—Submit detailed descriptions of environmental, meteorological, and oceanic conditions (+10 burden hours).

§ 250.470(d); 418—NEW—Submit detailed description concerning weather and ice forecasting for all phases; etc., (+6 hours).

One commenter suggested the regulations should implement performance based requirements for well containment, which recognizes acceptable alternatives to mud line cellars. BSEE agrees with the importance of allowing for the use of technology that is best suited to an operator's plan and has changed the burden as follows:

§ 250.720(c)(2)—NEW—Request approval to use an equivalent means rather than a well mudline cellar in areas of ice scour (+28 hours).

Another change that occurred to the BSEE information collection between the proposed and final rulemaking is the IC renewal for 30 CFR part 250, subpart S was initiated. When requests went out to industry for updated burdens, it was determined that the cost to conduct an audit has increased from $129,000 to $217,000. Based on a comment pertaining to the Regulatory Impact Analyses, it was decided that a SEMS audit in the Arctic will cost $250,000 (+$121,000).

BSEE Information Collection—30 CFR Parts 250 and 254

The title of the collection of information for this rule is 30 CFR parts 250 and 254, Requirements for Exploratory Drilling on the Arctic Outer Continental Shelf. The OMB approved the collection under Control Number 1014–0027, expiration 06/30/2019, 779 hours, $250,000 non-hour cost burdens. The regulations establish requirements for safe, responsible, and environmentally protective Arctic OCS oil and gas exploration, and the information is used in our efforts to protect life and the environment, conserve natural resources, and prevent waste.

Potential respondents comprise Federal OCS oil, gas, and sulfur operators and lessees on the Arctic OCS. The frequency of response varies depending upon the requirement. Responses to this collection of information are mandatory; they are submitted on occasion, annually, or as a result of situations encountered, depending upon the requirement. The IC does not include questions of a sensitive nature. BSEE will protect proprietary information according to the Freedom of Information Act (5 U.S.C. 552) and DOI's implementing regulations (43 CFR part 2), 30 CFR part 252, and 30 CFR 250.197, which address disclosure of data and information to be made available to the public.

As stated previously, this rulemaking also pertains to several regulations. Once this rule becomes effective, the paperwork and non-hour cost burdens will be removed from this collection of information and consolidated with the IC burdens under OMB Control Numbers 30 CFR part 250, subpart A, 1014–0022, expiration 8/3/2017 (84,391 hours, $1,371,458 non-hour cost burdens); subpart D, 1014–0018, expiration 10/31/2017 (102,512 hours); subpart S, 1014–0017, expiration 11/30/2018 (2,238,164 hours, $5,220,000 non-hour cost burdens); and 30 CFR part 254, 1014–0007, expiration 11/30/2018 (74,461 hours) respectively; current collections can be viewed at *www.reginfo.gov/public/.*

BURDEN BREAKDOWN

Citation 30 CFR parts 250 and 254	Reporting and recordkeeping requirements	Hour burden	Average number of annual responses	Annual burden hours
	30 CFR Part 250, Subpart A			
141	Request approval to use new or alternative procedures, along with supporting documentation if applicable, including BAST not specifically covered elsewhere in regulatory requirements.	Burden covered under 30 CFR part 250, subpart A, 1014–0022.		0
188(c); 190	NEW—Provide BSEE immediate oral report of sea ice movement/conditions; start and termination of ice management activities; kicks or unexpected operational issues.	Oral 1.5	2 notifications	3
188(c); 190	NEW—Submit a written report within 24 hours after completing ice management activities.	Written 4	2 reports	8
Subtotal			4 responses	11
	30 CFR Part 250, Subpart C			
300(b)(1)(2)	Obtain approval to add petroleum-based substance to drilling mud system or approval for method of disposal of drill cuttings, sand, & other well solids, including those containing NORM.	Burden covered under APDs or APMs 1014–0025 or 1014–0026.		0
	30 CFR Part 250, Subpart D			
418	Additional information that is to be submitted with an APD is covered under the specific requirement listed in this burden table under 30 CFR 250.470			0
452(a), (b)	NEW—Immediately transmit real-time data gathering and monitoring to record, store, and transmit data relating to the BOP control system, fluid handling, downhole conditions; prior to well operations, notify BSEE of monitoring location and make data available to BSEE upon request.	12	1 transmittal	12
452(b)	NEW—Store and monitor all information relating to § 250.452(a); make data available to BSEE upon request.	1	2 wells × 138 drilling days = 276.	276

BURDEN BREAKDOWN—Continued

Citation 30 CFR parts 250 and 254	Reporting and recordkeeping requirements	Hour burden	Average number of annual responses	Annual burden hours
452(b)	Store and retain all monitoring records per requirements of §§ 250.466 and 467.	Burden covered under 30 CFR part 250, subpart D, 1014–0018.		0
470(a); 713; 418	NEW—Submit detailed descriptions of environmental, meteorologic, and oceanic conditions expected at well site(s); how drilling unit, equipment, and materials will be prepared for service; how the drilling unit will be in compliance with § 250.417.	20	1 submittal	20
470(b); 418	NEW—Submit detailed description of transitioning rig from being underway to drilling and vice versa.	4	2 each well–underway to drilling; drilling to underway = 4.	16
470(b); 418	NEW—Submit detailed description of any anticipated repair and maintenance plans for the drilling unit and equipment.	2	2 submittals	4
470(c); 418	NEW—Submit well specific drilling objectives, timelines, and updated contingency plans etc., for temporary abandonment.	4	2 submittals	8
470(d); 418	NEW—Submit detailed description concerning weather and ice forecasting for all phases; including how to ensure continuous awareness of weather/ice hazards at/between each well site; plans for managing ice hazards and responding to weather events; verification of capabilities.	12	1 submittal	12
470(e); 418; 472	NEW—Submit a detailed description of compliance with relief rig plans.	140	1 description	140
470(f); 471(c); 418	NEW—SCCE capabilities; submit equipment statement showing capable of controlling WCD; detailed description of your or your contractor's SCCE capabilities including operating assumptions and limitations; inventory of local and regional supplies and services, along with supplier relevant information; proof of contract or agreements for providing SCCE or supplies, services; detailed description of procedures for inspecting, testing, and maintaining SCCE; and detailed description of your plan ensuring all members of the team operating SCCE have received training to deploy and operate, include dates of prior and planned training.	60	2 submittals	120
470(g); 418	NEW—Submit a detailed description of utilizing best practices of API RP 2N during operations..	20	1 submittal	20
471(c); 470(f); 465(a)	NEW—Submit with your APM, a reevaluation of your SCCE capabilities if well design changes; include any new WCD rate and demonstrate that your SCCE capabilities will comply with § 250.470(f).	10	2 submittals	20
471(e)	NEW—Maintain all SCCE testing, inspection, and maintenance records for at least 10 years; make available to BSEE upon request.	20	2 records	40
471(f)	NEW—Maintain all records pertaining to use of SCCE during testing, training, and deployment activities for at least 3 years; make available to BSEE upon request.	20	2 records	40
472(c)	Request approval for alternative compliance for relief rig requirements.	Burden covered under 30 CFR part 250, subpart A, 1014–0022		0
720(c)(2)	NEW—Request approval to use an equivalent means other than a well mudline cellar in areas of ice scour.	14		2 request
Subtotal			299 responses	756
	30 CFR Part 250, Subpart S			
1920(b), (c), (f)	ASP audit for High Activity Operator. NOTE: An audit once every 3 years in POCSR and GOMR; an audit in the Arctic in every year in which drilling is conducted (and the audit would cost more in the Arctic than in POCSR or GOMR).	1 operator × $250,000 audit for high activity = $250,000.		
1920(c)	Submit to BSEE after completed audit, an audit report of findings and conclusions, including deficiencies and required supporting information/documentation.	Burden covered under 30 CFR part 250, subpart S, 1014–0017.		0
1920(d)	Submit/resubmit a copy of your CAP that will address deficiencies identified in audit.			

BURDEN BREAKDOWN—Continued

Citation 30 CFR parts 250 and 254	Reporting and recordkeeping requirements	Hour burden	Average number of annual responses	Annual burden hours
Subtotal			1 response	0
			$250,000 Non Hour Cost Burdens	
30 CFR Part 254, Subpart E				
55; 70; 80; 90	Submit spill response plan for OCS facilities with all information required in regulations and related documents.	Burden covered under 30 CFR part 254, 1014–0007.		0
80(c)	NEW—Submit a description of system used to maintain real-time location tracking for all response resources.	6	2 descriptions	12
90(a)	Include in your training and exercise activities the requirements of this section.	Burden covered under 30 CFR part 254, 1014–0007.		0
90(b)	Notify BSEE 60 days prior to handling, storing, or transporting oil.			
Subtotal			2 responses	12
Total Hour Burden			306 responses	779
			$250,000 Non-Hour Cost Burdens	

BOEM Information Collection—30 CFR Part 550

This final rulemaking adds new requirements for submitting EPs and other information before conducting oil and gas exploration drilling activities on the Arctic OCS. The title of the collection for the rulemaking is 30 CFR part 550, subpart B, Arctic OCS Activities. The OMB approved the collection under Control Number 1010–0189, expiration 06/30/2019, 3,930 hours, and no non-hour cost burdens.

Respondents for this rulemaking are Federal oil, gas, or sulfur lessees and/or operators on the Arctic OCS. Submissions are mandatory. BOEM collects the information to ensure that planned operations will be safe; will not adversely affect the marine, coastal, or human environments; will respond to the special conditions on the Arctic OCS; and will conserve the resources of the Arctic OCS. BOEM uses the information to ensure, through advanced planning, that operators are capable of safely operating in the unique environmental conditions of the Arctic and to make informed decisions on whether to approve EPs as submitted or whether modifications are necessary. BOEM also plans to share the preliminary information submitted in the IOP with other relevant agencies to provide them the opportunity to engage in constructive dialogue/feedback with operators, and each other, early in the process.

The burdens for the current planning requirements under 30 CFR part 550, subpart B, regulations are approved by OMB under Control Number 1010–0151 (432,512 hours, $3,939,435 non-hour costs; expiration 3/31/2018; the current collection can be viewed at *www.reginfo.gov/public/*). When these final regulations become effective, the new IC burdens will be consolidated into the existing collection for subpart B.

BURDEN BREAKDOWN

Citation 30 CFR part 550, subpart B	Reporting & recordkeeping requirement	Hour burden	Average number of annual responses	Annual burden hours
Arctic Integrated Operations Plan (IOP)				
New—204	For New Arctic OCS Exploration Activities: Submit IOP, including all required information.	2,880	1	2,880
Contents of Exploration Plans (EP)				
206	General requirements for plans.	Burdens already covered under plans in 1010–0151.		0
220	Submit Alaska-specific information..			
Expanded—220	For New Arctic OCS Exploration Activities: Submit required Arctic-specific information with EP, including confirmations.	350	1	350

BURDEN BREAKDOWN—Continued

Citation 30 CFR part 550, subpart B	Reporting & recordkeeping requirement	Hour burden	Average number of annual responses	Annual burden hours
Expanded—220	For Existing Arctic OCS Exploration Activities: Revise and resubmit Arctic-specific information, as required.	700	1	700
Total Burden	....	....	3	3,930

L. National Environmental Policy Act of 1969 (NEPA)

BOEM and BSEE developed a final Environmental Assessment (EA) and have determined this final rule does not have a significant impact on the quality of the human environment under the NEPA. The final EA and Finding of No Significant Impact is available in conjunction with this final rule at *www.regulations.gov* (BSEE–2013–0011).

M. Data Quality Act

In developing this rule, we did not conduct or use a study, experiment, or survey requiring peer review under the Data Quality Act (Pub. L. 106–554, app. C section 515, 114 Stat. 2763, 2763A–153–154).

The Bureaus received two comments on the Data Quality Act. One comment asserted the NPRM, the Draft EA and the initial RIA violated the Information Quality Act (IQA) peer review requirements as well as associated IQA Guidelines.

We disagree. The IQA applies to information disseminated by Federal agencies and establishes basic quality performance goals for such information.[50] However, the IQA is not applicable to this rulemaking, including the associated Draft EA or initial RIA, because the Bureaus did not disseminate materials with information subject to the IQA. The rulemaking and associated analyses contain information the Bureaus relied on during the formulation of the final rule. The Bureaus made the proposed rulemaking publicly available and sought public input. However, we did not "disseminate" (*i.e.*, conduct an agency-sponsored distribution of information to the public) a study, analysis, or other [similar] information as part of this rulemaking that implicates the IQA.[51] Accordingly, the IQA does not apply to the actions associated with this rulemaking.

The second comment recommended the IC Requests in this final rule should be withdrawn by DOI or denied by OMB because the DOI burden estimates and the rest of the PRA analysis violate the IQA requirement for peer review as well as OMB and DOI IQA guidelines.

BOEM and BSEE disagree. The IC Requests are publicly available, but they are not disseminated to the public as that term is used in the IQA. In other words, the ICRs reflect information on which the Bureaus relied in reaching their decision, not an agency-sponsored distribution of information to the public. Therefore, the IQA, including the peer-review provisions, is not implicated by the content of the Bureaus' IC Request submissions to OMB. Also, the Bureaus' IC Requests have reasonably demonstrated that they have practical utility under the OMB definition, and the commenter provides no legitimate legal reason for recommending their withdrawal.

N. Effects on the Nation's Energy Supply (E.O. 13211)

This rule is not a significant energy action under the definition of that term in E.O. 13211 because:

1. It is not likely to have a significant adverse effect on the supply, distribution or use of energy; and

2. It has not been designated as a significant energy action by the Administrator of OIRA.

Thus, a Statement of Energy Effects is not required.

Due to the inherent practical difficulties of exploration and production in the Arctic, to date there has been minimal exploration activity, and very little production of oil and gas, on the Arctic OCS. The only existing oil production from the Arctic OCS is through the Northstar Island facility in State of Alaska waters.

The regulations' cumulative effects (including baseline provisions) are not expected to affect long-term activity. This regulation establishes specific guidelines that protect the Arctic environment and makes explicit the requirements that operators will face. Protecting the Arctic region from a catastrophic oil spill is imperative for the long-term hydrocarbon development of the region.

We note that, although the rule might have a short-term impact on Arctic OCS exploration and development, other factors over which BOEM and BSEE have no control are likely to have a much greater effect on the rate of oil production from the Arctic OCS region. The primary external factor is the market price of oil and gas. The pace of exploration and development responds to changes in oil prices, with the pace slowing down when prices are decreasing and the pace accelerating when prices are rising.

The Arctic region of Alaska has not previously relied on the type of offshore drilling regulated by this final rule for economic development or well-being. The OCSLA states that the policy of the U.S. is both to make the OCS available for production and development as well as to ensure that operations are conducted safely. Lessees, particularly in the Arctic, obtain OCS leases and pursue exploration with a full understanding of this dynamic. This rulemaking reflects the Bureaus' reasonable and appropriate fulfillment of their multifaceted OCSLA mandates.

O. Clarity of This Regulation

We are required by E.O. 12866, E.O. 12988, and by the Presidential Memorandum of June 1, 1998, to write all rules in plain language. This means that each rule we publish must:

1. Be logically organized;
2. Use the active voice to address readers directly;
3. Use clear language rather than jargon;
4. Be divided into short sections and sentences; and
5. Use lists and tables wherever possible.

List of Subjects

30 CFR Part 250

Administrative practice and procedure, Continental shelf, Environmental impact statements, Environmental protection, Incorporation by reference, Investigations, Government contracts, Oil and gas exploration, Penalties, Pipelines, Reporting and recordkeeping requirements, Sulfur.

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[50] Treasury and General Government Appropriations Act for Fiscal Year 2001, sec. 515 (Pub. L. 106–554) (Dec. 21, 2000).

[51] See OMB regulations at 5 CFR part 1320, *Controlling Paperwork Burdens on the Public.*

30 CFR Part 254

Continental shelf, Environmental protection, Intergovernmental relations, Oil and gas exploration, Oil pollution, Pipelines, Reporting and recordkeeping requirements.

30 CFR Part 550

Administrative practice and procedure, Continental shelf, Environmental impact statements, Environmental protection, Government contracts, Incorporation by reference, Investigations, Oil and gas exploration, Penalties, Pipelines, Reporting and recordkeeping requirements, Sulfur.

Dated: June 28, 2016.

Janice M. Schneider,

Assistant Secretary, Land and Minerals Management.

For the reasons stated in the preamble, BOEM and BSEE amend 30 CFR parts 250, 254, and 550 as follows:

Title 30—Mineral Resources

CHAPTER II—BUREAU OF SAFETY AND ENVIRONMENTAL ENFORCEMENT, DEPARTMENT OF THE INTERIOR

PART 250—OIL AND GAS AND SULFUR OPERATIONS IN THE OUTER CONTINENTAL SHELF

■ 1. The authority citation for 30 CFR part 250 is revised to read as follows:

Authority: 30 U.S.C. 1751, 31 U.S.C. 9701, 33 U.S.C. 1321(j)(1)(C), 43 U.S.C. 1334.

■ 2. Amend § 250.105 by:

■ a. Revising the definition of "District Manager"; and

■ b. Adding definitions for "Arctic OCS", "Arctic OCS conditions", "Cap and flow system", "Capping stack", "Containment dome", and "Source control and containment equipment (SCCE)" in alphabetical order.

The revision and additions read as follows:

§ 250.105 Definitions.

* * * * *

Arctic OCS means the Beaufort Sea and Chukchi Sea Planning Areas (for more information on these areas, *see* the Proposed Final OCS Oil and Gas Leasing Program for 2012–2017 (June 2012) at *http://www.boem.gov/Oil-and-Gas-Energy-Program/Leasing/Five-Year-Program/2012-2017/Program-Area-Maps/index.aspx*).

Arctic OCS conditions means, for the purposes of this part, the conditions operators can reasonably expect during operations on the Arctic OCS. Such conditions, depending on the time of year, include, but are not limited to: Extreme cold, freezing spray, snow, extended periods of low light, strong winds, dense fog, sea ice, strong currents, and dangerous sea states. Remote location, relative lack of infrastructure, and the existence of subsistence hunting and fishing areas are also characteristic of the Arctic region.

* * * * *

Cap and flow system means an integrated suite of equipment and vessels, including a capping stack and associated flow lines, that, when installed or positioned, is used to control the flow of fluids escaping from the well by conveying the fluids to the surface to a vessel or facility equipped to process the flow of oil, gas, and water. A cap and flow system is a high pressure system that includes the capping stack and piping necessary to convey the flowing fluids through the choke manifold to the surface equipment.

Capping stack means a mechanical device, including one that is pre-positioned, that can be installed on top of a subsea or surface wellhead or blowout preventer to stop the uncontrolled flow of fluids into the environment.

* * * * *

Containment dome means a non-pressurized container that can be used to collect fluids escaping from the well or equipment below the sea surface or from seeps by suspending the device over the discharge or seep location. The containment dome includes all of the equipment necessary to capture and convey fluids to the surface.

* * * * *

District Manager means the BSEE officer with authority and responsibility for operations or other designated program functions for a district within a BSEE Region. For activities on the Alaska OCS, any reference in this part to District Manager means the BSEE Regional Supervisor.

* * * * *

Source control and containment equipment (SCCE) means the capping stack, cap and flow system, containment dome, and/or other subsea and surface devices, equipment, and vessels the collective purpose of which is to control a spill source and stop the flow of fluids into the environment or to contain fluids escaping into the environment. "Surface devices" refers to equipment mounted or staged on a barge, vessel, or facility to separate, treat, store and/or dispose of fluids conveyed to the surface by the cap and flow system or the containment dome. "Subsea devices" includes, but is not limited to, remotely operated vehicles, anchors, buoyancy equipment, connectors, cameras, controls and other subsea equipment necessary to facilitate the deployment, operation, and retrieval of the SCCE. The SCCE does not include a blowout preventer.

* * * * *

■ 3. Amend § 250.188 by adding paragraph (c) to read as follows:

§ 250.188 What incidents must I report to BSEE and when must I report them?

* * * * *

(c) On the Arctic OCS, in addition to the requirements of paragraphs (a) and (b) of this section, you must provide to the BSEE inspector on location, if one is present, or to the Regional Supervisor, both of the following:

(1) An immediate oral report if any of the following occur:

(i) Any sea ice movement or condition that has the potential to affect your operation or trigger ice management activities;

(ii) The start and termination of ice management activities; or

(iii) Any "kicks" or operational issues that are unexpected and could result in the loss of well control.

(2) Within 24 hours after completing ice management activities, a written report of such activities that conforms to the content requirements in § 250.190.

■ 4. Amend § 250.198 by adding paragraph (h)(95) to read as follows:

§ 250.198 Documents incorporated by reference.

* * * * *

(h) * * *

(95) ANSI/API RP 2N, Third Edition, "Recommended Practice for Planning, Designing, and Constructing Structures and Pipelines for Arctic Conditions", Third Edition, April 2015; incorporated by reference at § 250.470(g);

* * * * *

■ 5. Amend § 250.300 by revising paragraphs (b)(1) and (2) to read as follows:

§ 250.300 Pollution prevention.

* * * * *

(b)(1) The District Manager may restrict the rate of drilling fluid discharges or prescribe alternative discharge methods. The District Manager may also restrict the use of components that could cause unreasonable degradation to the marine environment. No petroleum-based substances, including diesel fuel, may be added to the drilling mud system without prior approval of the District Manager. For Arctic OCS exploratory drilling, you must capture all petroleum-based mud to prevent its discharge into the marine environment. The Regional Supervisor may also require you to capture, during your Arctic OCS exploratory drilling operations, all water-based mud from operations after completion of the hole for the conductor casing to prevent its discharge into the marine environment, based on various factors including, but not limited to:

(i) The proximity of your exploratory drilling operation to subsistence hunting and fishing locations;

(ii) The extent to which discharged mud may cause marine mammals to alter their migratory patterns in a manner that impedes subsistence users' access to, or use of, those resources, or increases the risk of injury to subsistence users; or

(iii) The extent to which discharged mud may adversely affect marine mammals, fish, or their habitat.

(2) You must obtain approval from the District Manager of the method you plan to use to dispose of drill cuttings, sand, and other well solids. For Arctic OCS exploratory drilling, you must capture all cuttings from operations that utilize petroleum-based mud to prevent their discharge into the marine environment. The Regional Supervisor may also require you to capture, during your Arctic OCS exploratory drilling operations, all cuttings from operations that utilize water-based mud after completion of the hole for the conductor casing to prevent their discharge into the marine environment, based on various factors including, but not limited to:

(i) The proximity of your exploratory drilling operation to subsistence hunting and fishing locations;

(ii) The extent to which discharged cuttings may cause marine mammals to alter their migratory patterns in a manner that impedes subsistence users' access to, or use of, those resources, or increases the risk of injury to subsistence users; or

(iii) The extent to which discharged cuttings may adversely affect marine mammals, fish, or their habitat.

* * * * *

■ 6. Amend § 250.418 by adding paragraph (j) to read as follows:

§ 250.418 What additional information must I submit with my APD?

* * * * *

(j) For Arctic OCS exploratory drilling operations, you must provide the information required by § 250.470.

■ 7. Add § 250.452 to read as follows:

§ 250.452 What are the real-time monitoring requirements for Arctic OCS exploratory drilling operations?

(a) When conducting exploratory drilling operations on the Arctic OCS, you must gather and monitor real-time data using an independent, automatic, and continuous monitoring system capable of recording, storing, and transmitting data regarding the following:

(1) The BOP control system;

(2) The well's fluid handling systems on the rig; and

(3) The well's downhole conditions as monitored by a downhole sensing system, when such a system is installed.

(b) During well operations, you must transmit the data identified in paragraph (a) of this section as they are gathered, barring unforeseeable or unpreventable interruptions in transmission, and have the capability to monitor the data onshore, using qualified personnel. Onshore personnel who monitor real-time data must have the capability to contact rig personnel during operations. After well operations, you must store the data at a designated location for recordkeeping purposes as required in §§ 250.740 and 250.741. You must provide BSEE with access to your real-time monitoring data onshore upon request.

■ 8. Add an undesignated center heading and §§ 250.470 through 250.473 to subpart D to read as follows:

Additional Arctic OCS Requirements

§ 250.470 What additional information must I submit with my APD for Arctic OCS exploratory drilling operations?

In addition to complying with all other applicable requirements included in this part, you must provide with your APD all of the following information pertaining to your proposed Arctic OCS exploratory drilling:

(a) A detailed description of:

(1) The environmental, meteorological, and oceanic conditions you expect to encounter at the well site(s);

(2) How you will prepare your equipment, materials, and drilling unit for service in the conditions identified in paragraph (a)(1) of this section, and how your drilling unit will be in compliance with the requirements of § 250.713.

(b) A detailed description of all operations necessary in Arctic OCS conditions to transition the rig from being under way to conducting drilling operations and from ending drilling operations to being under way, as well as any anticipated repair and maintenance plans for the drilling unit and equipment. You should include, among other things, a description of how you plan to:

(1) Recover the subsea equipment, including the marine riser and the lower marine riser package;

(2) Recover the BOP;

(3) Recover the auxiliary sub-sea controls and template;

(4) Lay down the drill pipe and secure the drill pipe and marine riser;

(5) Secure the drilling equipment;

(6) Transfer the fluids for transport or disposal;

(7) Secure ancillary equipment like the draw works and lines;

(8) Refuel or transfer fuel;

(9) Offload waste;

(10) Recover the Remotely Operated Vehicles;

(11) Pick up the oil spill prevention booms and equipment; and

(12) Offload the drilling crew.

(c) A description of well-specific drilling objectives, timelines, and updated contingency plans for temporary abandonment of the well, including but not limited to the following:

(1) When you will spud the particular well (*i.e.,* begin drilling operations at the well site) identified in the APD;

(2) How long you will take to drill the well;

(3) Anticipated depths and geologic targets, with timelines;

(4) When you expect to set and cement each string of casing;

(5) When and how you would log the well;

(6) Your plans to test the well;

(7) When and how you intend to abandon the well, including specifically addressing your plans for how to move the rig off location and how you will meet the requirements of § 250.720(c);

(8) A description of what equipment and vessels will be involved in the process of temporarily abandoning the well due to ice; and

(9) An explanation of how you will integrate these elements into your overall program.

(d) A detailed description of your weather and ice forecasting capability for all phases of the drilling operation, including:

(1) How you will ensure your continuous awareness of potential weather and ice hazards at, and during transition between, wells;

(2) Your plans for managing ice hazards and responding to weather events; and

(3) Verification that you have the capabilities described in your BOEM-approved EP.

(e) A detailed description of how you will comply with the requirements of § 250.472.

(f) A statement that you own, or have a contract with a provider for, source control and containment equipment (SCCE), which is capable of controlling and/or containing a worst case discharge, as described in your BOEM-approved EP, when proposing to use a MODU to conduct exploratory drilling operations on the Arctic OCS. The following information must be included in your SCCE submittal:

(1) A detailed description of your or your contractor's SCCE capability to stop or contain flow from an out-of-control well, including your operating assumptions and limitations; your access to and ability to deploy, in accordance with § 250.471, all necessary SCCE; and your ability to evaluate the performance of the well design to determine how you can achieve a full shut-in without having reservoir fluids discharged into the environment;

(2) An inventory of the local and regional SCCE, supplies, and services that you own or for which you have a contract with a provider. You must identify each supplier of such equipment and services and provide their locations and telephone numbers;

(3) Where applicable, proof of contracts or membership agreements with cooperatives, service providers, or other contractors who will provide you with the necessary SCCE or related supplies and services if you do not possess them. The contract or membership agreement must include provisions for ensuring the availability of the personnel and/or equipment on a 24-hour per day basis while you are drilling below or working below the surface casing;

(4) A detailed description of the procedures you plan to use to inspect, test, and maintain your SCCE; and

(5) A detailed description of your plan to ensure that all members of your operating team, who are responsible for operating the SCCE, have received the necessary training to deploy and operate such equipment in Arctic OCS conditions and demonstrate ongoing proficiency in source control operations. You must also identify and include the dates of prior and planned training.

(g) Where it does not conflict with other requirements of this subpart, and except as provided in paragraphs (g)(1) through (11) of this section, you must comply with the requirements of API RP 2N, Third Edition "Planning, Designing, and Constructing Structures and Pipelines for Arctic Conditions" (incorporated by reference as specified in § 250.198), and provide a detailed description of how you will utilize the best practices included in API RP 2N during your exploratory drilling operations. You are not required to incorporate the following sections of API RP 2N into your drilling operations:

(1) Sections 6.6.3 through 6.6.4;

(2) The foundation recommendations in Section 8.4;

(3) Section 9.6;

(4) The recommendations for permanently moored systems in Section 9.7;

(5) The recommendations for pile foundations in Section 9.10;

(6) Section 12;

(7) Section 13.2.1;

(8) Sections 13.8.1.1, 13.8.2.1, 13.8.2.2, 13.8.2.4 through 13.8.2.7;

(9) Sections 13.9.1, 13.9.2, 13.9.4 through 13.9.8;

(10) Sections 14 through 16; and

(11) Section 18.

§ 250.471 What are the requirements for Arctic OCS source control and containment?

You must meet the following requirements for all exploration wells drilled on the Arctic OCS:

(a) If you use a MODU when drilling below or working below the surface casing, you must have access to the following SCCE capable of stopping or capturing the flow of an out-of-control well:

(1) A capping stack, positioned to ensure that it will arrive at the well location within 24 hours after a loss of well control and can be deployed as directed by the Regional Supervisor pursuant to paragraph (h) of this section;

(2) A cap and flow system, positioned to ensure that it will arrive at the well location within 7 days after a loss of well control and can be deployed as directed by the Regional Supervisor pursuant to paragraph (h) of this section. The cap and flow system must be designed to capture at least the amount of hydrocarbons equivalent to the calculated worst case discharge rate referenced in your BOEM-approved EP; and

(3) A containment dome, positioned to ensure that it will arrive at the well location within 7 days after a loss of well control and can be deployed as directed by the Regional Supervisor pursuant to paragraph (h) of this section. The containment dome must have the capacity to pump fluids without relying on buoyancy.

(b) You must conduct a monthly stump test of dry-stored capping stacks. If you use a pre-positioned capping stack, you must conduct a stump test prior to each installation on each well.

(c) As required by § 250.465(a), if you propose to change your well design, you must submit an APM. For Arctic OCS operations, your APM must include a reevaluation of your SCCE capabilities for any new Worst Case Discharge (WCD) rate, and a demonstration that your SCCE capabilities will meet the criteria in § 250.470(f) under the changed well design.

(d) You must conduct tests or exercises of your SCCE, including deployment of your SCCE, when directed by the Regional Supervisor.

(e) You must maintain records pertaining to testing, inspection, and maintenance of your SCCE for at least 10 years and make the records available to any authorized BSEE representative upon request.

(f) You must maintain records pertaining to the use of your SCCE during testing, training, and deployment activities for at least 3 years and make the records available to any authorized BSEE representative upon request.

(g) Upon a loss of well control, you must initiate transit of all SCCE identified in paragraph (a) of this section to the well.

(h) You must deploy and use SCCE when directed by the Regional Supervisor.

(i) Operators may request approval of alternate procedures or equipment to the SCCE requirements of subparagraph (a) of this section in accordance with § 250.141. The operator must show and document that the alternate procedures or equipment will provide a level of safety and environmental protection that will meet or exceed the level of safety and environmental protection required by BSEE regulations, including demonstrating that the alternate procedures or equipment will be capable of stopping or capturing the flow of an out-of-control well.

§ 250.472 What are the relief rig requirements for the Arctic OCS?

(a) In the event of a loss of well control, the Regional Supervisor may direct you to drill a relief well using the relief rig able to kill and permanently plug an out-of-control well as described in your APD. Your relief rig must comply with all other requirements of this part pertaining to drill rig characteristics and capabilities, and it must be able to drill a relief well under anticipated Arctic OCS conditions.

(b) When you are drilling below or working below the surface casing during Arctic OCS exploratory drilling operations, you must have access to a relief rig, different from your primary drilling rig, staged in a location such that it can arrive on site, drill a relief well, kill and abandon the original well, and abandon the relief well prior to expected seasonal ice encroachment at the drill site, but no later than 45 days after the loss of well control.

(c) Operators may request approval of alternative compliance measures to the relief rig requirement in accordance with § 250.141. The operator must show and document that the alternate compliance measure will meet or exceed the level of safety and environmental protection required by BSEE regulations, including demonstrating that the alternate compliance measure will be able to kill and permanently plug an out-of-control well.

§ 250.473 What must I do to protect health, safety, property, and the environment while operating on the Arctic OCS?

In addition to the requirements set forth in § 250.107, when conducting exploratory drilling operations on the Arctic OCS, you must protect health, safety, property, and the environment by using the following:

(a) Equipment and materials that are rated or de-rated for service under conditions that can be reasonably expected during your operations; and

(b) Measures to address human factors associated with weather conditions that can be reasonably expected during your operations including, but not limited to, provision of proper attire and equipment, construction of protected work spaces, and management of shifts.

■ 9. Amend § 250.720 by adding paragraph (c) to read as follows:

§ 250.720 When and how must I secure a well?

* * * * *

(c) For Arctic OCS exploratory drilling operations, in addition to the requirements of paragraphs (a) and (b) of this section:

(1) If you move your drilling rig off a well prior to completion or permanent abandonment, you must ensure that any equipment left on, near, or in a wellbore that has penetrated below the surface casing is positioned in a manner to:

(i) Protect the well head; and

(ii) Prevent or minimize the likelihood of compromising the down-hole integrity of the well or the effectiveness of the well plugs.

(2) In areas of ice scour you must use a well mudline cellar or an equivalent means of minimizing the risk of damage to the well head and wellbore. BSEE may approve an equivalent means that will meet or exceed the level of safety and environmental protection provided by a mudline cellar if the operator can show that utilizing a mudline cellar would compromise the stability of the rig, impede access to the well head during a well control event, or otherwise create operational risks.

■ 10. Amend § 250.1920 by:

■ a. Adding a sentence at the end of paragraphs (b)(5), (c), and (d); and

■ b. Adding paragraphs (f) and (g).

The additions read as follows:

§ 250.1920 What are the auditing requirements for my SEMS program?

* * * * *

(b) * * *

(5) * * * For exploratory drilling operations taking place on the Arctic OCS, you must conduct an audit, consisting of an onshore portion and an offshore portion, including all related infrastructure, once per year for every year in which drilling is conducted.

* * * * *

(c) * * * For exploratory drilling operations taking place on the Arctic OCS, you must submit an audit report of the audit findings, observations, deficiencies and conclusions for the onshore portion of your audit no later than March 1 in any year in which you plan to drill, and for the offshore portion of your audit, within 30 days of the close of the audit.

(d) * * * For exploratory drilling operations taking place on the Arctic OCS, you must provide BSEE with a copy of your CAP for addressing deficiencies or nonconformities identified in the onshore portion of the audit no later than March 1 in any year in which you plan to drill, and for the offshore portion of your audit, within 30 days of the close of the audit.

* * * * *

(f) For exploratory drilling operations taking place on the Arctic OCS, during the offshore portion of each audit, 100 percent of the facilities operated must be audited while drilling activities are underway. You must start and close the offshore portion of the audit for each facility within 30 days after the first spudding of the well or entry into an existing wellbore for any purpose from that facility.

(g) For exploratory drilling operations taking place on the Arctic OCS, if BSEE determines that the CAP or progress toward implementing the CAP is not satisfactory, BSEE may order you to shut down all or part of your operations.

PART 254—OIL-SPILL RESPONSE REQUIREMENTS FOR FACILITIES LOCATED SEAWARD OF THE COAST LINE

■ 11. The authority citation for 30 CFR part 254 continues to read as follows:

Authority: 33 U.S.C. 1321.

■ 12. Amend § 254.6 by:

■ a. Revising the definition of "Adverse weather conditions;" and

■ b. Adding definitions for "Arctic OCS" and "Ice intervention practices" in alphabetical order.

The revision and additions read as follows:

§ 254.6 Definitions.

* * * * *

Adverse weather conditions means, for the purposes of this part, weather conditions found in the operating area that make it difficult for response equipment and personnel to clean up or remove spilled oil or hazardous substances. These conditions include, but are not limited to: fog, inhospitable water and air temperatures, wind, sea ice, extreme cold, freezing spray, snow, currents, sea states, and extended periods of low light. Adverse weather conditions do not refer to conditions under which it would be dangerous or impossible to respond to a spill, such as a hurricane.

Arctic OCS means the Beaufort Sea and Chukchi Sea Planning Areas (for more information on these areas, *see* the Proposed Final OCS Oil and Gas Leasing Program for 2012–2017 (June 2012) at *http://www.boem.gov/Oil-and-Gas-Energy-Program/Leasing/Five-Year-Program/2012-2017/Program-Area-Maps/index.aspx*).

* * * * *

Ice intervention practices mean the equipment, vessels, and procedures used to increase oil encounter rates and the effectiveness of spill response techniques and equipment when sea ice is present.

* * * * *

■ 13. Add § 254.55 to subpart D to read as follows:

§ 254.55 Spill response plans for facilities located in Alaska State waters seaward of the coast line in the Chukchi and Beaufort Seas.

Response plans for facilities conducting exploratory drilling operations from a MODU seaward of the coast line in Alaska State waters in the Chukchi and Beaufort Seas must follow the requirements contained within subpart E of this part, in addition to the other requirements of this subpart. Such response plans must address how the source control procedures selected to comply with State law will be integrated into the planning, training, and exercise requirements of §§ 254.70(a), 254.90(a), and 254.90(c), in the event that the proposed operations do not incorporate the capping stack, cap and flow system, containment dome, and/or other similar subsea and surface devices and equipment and vessels referenced in those sections.

■ 14. Add subpart E to read as follows:

Subpart E—Oil-Spill Response Requirements for Facilities Located on the Arctic OCS

Sec.
254.65 Purpose.
254.66 through 254.69 [Reserved]
254.70 What are the additional requirements for facilities conducting exploratory drilling from a MODU on the Arctic OCS?
254.71 through 254.79 [Reserved]
254.80 What additional information must I include in the "Emergency response action plan" section for facilities conducting exploratory drilling from a MODU on the Arctic OCS?
254.81 through 254.89 [Reserved]
254.90 What are the additional requirements for exercises of your response personnel and equipment for facilities conducting exploratory drilling from a MODU on the Arctic OCS?

Subpart E—Oil-Spill Response Requirements for Facilities Located on the Arctic OCS

§ 254.65 Purpose.

This subpart describes the additional requirements for preparing OSRPs and maintaining oil spill preparedness for facilities conducting exploratory drilling operations from a mobile offshore drilling unit (MODU) on the Arctic OCS.

§§ 254.66 through 254.69 [Reserved]

§ 254.70 What are the additional requirements for facilities conducting exploratory drilling from a MODU on the Arctic OCS?

In addition to meeting the applicable requirements of this part, your OSRP must:

(a) Describe how the relevant personnel, equipment, materials, and support vessels associated with the capping stack, cap and flow system, containment dome, and other similar subsea and surface devices and equipment and vessels will be integrated into oil spill response incident action planning;

(b) Describe how you will address human factors, such as cold stress and cold related conditions, associated with oil spill response activities in adverse weather conditions and their impacts on decision-making and health and safety; and

(c) Undergo plan-holder review prior to handling, storing, or transporting oil in connection with seasonal exploratory drilling activities, and all resulting modifications must be submitted to the Regional Supervisor. If this review does not result in modifications, you must inform the Regional Supervisor in writing that there are no changes. The requirements of this paragraph (c) are in lieu of the requirements in § 254.30(a).

§§ 254.71 through 254.79 [Reserved]

§ 254.80 What additional information must I include in the "Emergency response action plan" section for facilities conducting exploratory drilling from a MODU on the Arctic OCS?

In addition to the requirements in § 254.23, you must include the following information in the emergency response action plan section of your OSRP:

(a) A description of your ice intervention practices and how they will improve the effectiveness of the oil spill response options and strategies that are listed in your OSRP in the presence of sea ice. When developing the ice intervention practices for your OSRP, you must consider, at a minimum, the use of specialized tactics, modified response equipment, ice management assist vessels, and technologies for the identification, tracking, containment and removal of oil in ice.

(b) On areas of the Arctic OCS where a planned shore-based response would not satisfy § 254.1(a):

(1) A list of all resources required to ensure an effective offshore-based response capable of operating in adverse weather conditions. This list must include a description of how you will ensure the shortest possible transit times, including but not limited to establishing an offshore resource management capability (*e.g.*, sea-based staging, maintenance, and berthing logistics); and

(2) A list and description of logistics resupply chains, including waste management, that effectively factor in the remote and limited infrastructure that exists in the Arctic and ensure you can adequately sustain all oil spill response activities for the duration of the response. The components of the logistics supply chain include, but are not limited to:

(i) Personnel and equipment transport services;

(ii) Airfields and types of aircraft that can be supported;

(iii) Capabilities to mobilize supplies (*e.g.*, response equipment, fuel, food, fresh water) and personnel to the response sites;

(iv) Onshore staging areas, storage areas that may be used en-route to staging areas, and camp facilities to support response personnel conducting offshore, nearshore and shoreline response; and

(v) Management of recovered fluid and contaminated debris and response materials (*e.g.*, oiled sorbents), as well as waste streams generated at offshore and on-shore support facilities (*e.g.*, sewage, food, and medical).

(c) A description of the system you will use to maintain real-time location tracking for all response resources while operating, transiting, or staging/maintaining such resources during a spill response.

§§ 254.81 through 254.89 [Reserved]

§ 254.90 What are the additional requirements for exercises of your response personnel and equipment for facilities conducting exploratory drilling from a MODU on the Arctic OCS?

In addition to the requirements in § 254.42, the following requirements apply to exercises for your response personnel and equipment for facilities conducting exploratory drilling from a MODU on the Arctic OCS:

(a) You must incorporate the personnel, materials, and equipment identified in § 254.70(a), the safe working practices identified in § 254.70(b), the ice intervention practices described in § 254.80(a), the offshore-based response requirements in § 254.80(b), and the resource tracking requirements in § 254.80(c) into your spill-response training and exercise activities.

(b) For each season in which you plan to conduct exploratory drilling operations from a MODU on the Arctic OCS, you must notify the Regional Supervisor 60 days prior to handling, storing, or transporting oil.

(c) After the Regional Supervisor receives notice pursuant to § 254.90(b), the Regional Supervisor may direct you to deploy and operate your spill response equipment and/or your capping stack, cap and flow system, and containment dome, and other similar subsea and surface devices and equipment and vessels, as part of announced or unannounced exercises or compliance inspections. For the purposes of this section, spill response equipment does not include the use of blowout preventers, diverters, heavy weight mud to kill the well, relief wells, or other similar conventional well control options.

CHAPTER V—BUREAU OF OCEAN ENERGY MANAGEMENT, DEPARTMENT OF THE INTERIOR

PART 550—OIL AND GAS AND SULFUR OPERATIONS IN THE OUTER CONTINENTAL SHELF

■ 15. The authority citation for 30 CFR part 550 is revised to read as follows:

Authority: 30 U.S.C. 1751; 31 U.S.C. 9701; 43 U.S.C. 1334.

■ 16. Amend § 550.105 by adding definitions for "Arctic OCS" and "Arctic OCS conditions" in alphabetical order to read as follows:

§ 550.105 Definitions.

* * * * *

Arctic OCS means the Beaufort Sea and Chukchi Sea Planning Areas (for more information on these areas, *see* the Proposed Final OCS Oil and Gas Leasing Program for 2012–2017 (June 2012) at *http://www.boem.gov/Oil-and-Gas-Energy-Program/Leasing/Five-Year-Program/2012–2017/Program-Area-Maps/index.aspx*).

Arctic OCS conditions means, for the purposes of this part, the conditions operators can reasonably expect during operations on the Arctic OCS. Such conditions, depending on the time of year, include, but are not limited to: extreme cold, freezing spray, snow, extended periods of low light, strong winds, dense fog, sea ice, strong currents, and dangerous sea states. Remote location, relative lack of infrastructure, and the existence of subsistence hunting and fishing areas are also characteristic of the Arctic region.

* * * * *

■ 17. Amend § 550.200 in paragraph (a) by adding the term "IOP" in alphabetical order:

§ 550.200 Definitions.

* * * * *

(a) * * *

IOP means Integrated Operations Plan.

* * * * *

■ 18. Add § 550.204 to read as follows:

§ 550.204 When must I submit my IOP for proposed Arctic exploratory drilling operations and what must the IOP include?

If you propose exploratory drilling activities on the Arctic OCS, you must submit an Integrated Operations Plan (IOP) to the Regional Supervisor at least 90 days prior to filing your EP. Your IOP must describe how your exploratory drilling program will be designed and conducted in an integrated manner that accounts for Arctic OCS conditions and include the following information:

(a) A description of how all vessels and equipment will be designed, built, and/or modified to account for Arctic OCS conditions;

(b) A schedule of your exploratory drilling program, including contractor work on critical components of your program;

(c) A description of your mobilization and demobilization operations, including tow plans that account for Arctic OCS conditions, as well as your general maintenance schedule for vessels and equipment;

(d) A description of your exploratory drilling program objectives and timelines for each objective, including general plans for abandonment of the well(s), such as:

(1) Contingency plans for temporary abandonment in the event of ice encroachment at the drill site;

(2) Plans for permanent abandonment; and

(3) Plans for temporary seasonal abandonment.

(e) A description of your weather and ice forecasting capabilities for all phases of the exploration program, including a description of how you would respond to and manage ice hazards and weather events;

(f) A description of work to be performed by contractors supporting your exploration drilling program (including mobilization and demobilization), including:

(1) How such work will be designed or modified to account for Arctic OCS conditions; and

(2) Your concepts for contractor management, oversight, and risk management.

(g) A description of how you will ensure operational safety while working in Arctic OCS conditions, including but not limited to:

(1) The safety principles that you intend to apply to yourself and your contractors;

(2) The accountability structure within your organization for implementing such principles;

(3) How you will communicate such principles to your employees and contractors; and

(4) How you will determine successful implementation of such principles.

(h) Information regarding your preparations and plans for staging of oil spill response assets;

(i) A description of your efforts to minimize impacts of your exploratory drilling operations on local community infrastructure, including but not limited to housing, energy supplies, and services; and

(j) A description of whether and to what extent your project will rely on local community workforce and spill cleanup response capacity.

■ 19. Revise § 550.206 to read as follows:

§ 550.206 How do I submit the IOP, EP, DPP, or DOCD?

(a) *Number of copies.* When you submit an IOP, EP, DPP, or DOCD to BOEM, you must provide:

(1) Four copies that contain all required information (proprietary copies);

(2) Eight copies for public distribution (public information copies) that omit information that you assert is exempt from disclosure under the Freedom of Information Act (FOIA) (5 U.S.C. 552) and the implementing regulations (43 CFR part 2); and

(3) Any additional copies that may be necessary to facilitate review of the IOP, EP, DPP, or DOCD by certain affected States and other reviewing entities.

(b) *Electronic submission.* You may submit part or all of your IOP, EP, DPP, or DOCD and its accompanying information electronically. If you prefer to submit your IOP, EP, DPP, or DOCD electronically, ask the Regional Supervisor for further guidance.

(c) *Withdrawal after submission.* You may withdraw your proposed IOP, EP, DPP, or DOCD at any time for any reason. Notify the appropriate BOEM OCS Region if you do.

■ 20. Amend § 550.220 by revising paragraph (a) and adding paragraph (c) to read as follows:

§ 550.220 If I propose activities in the Alaska OCS Region, what planning information must accompany the EP?

* * * * *

(a) *Emergency plans.* A description of your emergency plans to respond to a fire, explosion, personnel evacuation, or loss of well control, as well as a loss or disablement of a drilling unit, and loss of or damage to a support vessel, offshore vehicle, or aircraft.

* * * * *

(c) If you propose exploration activities on the Arctic OCS, the following planning information must also accompany your EP:

(1) *Suitability for Arctic OCS conditions.* A description of how your exploratory drilling activities will be designed and conducted in a manner that accounts for Arctic OCS conditions and how such activities will be managed and overseen as an integrated endeavor.

(2) *Ice and weather management.* A description of your weather and ice forecasting and management plans for all phases of your exploratory drilling activities, including:

(i) A description of how you will respond to and manage ice hazards and weather events;

(ii) Your ice and weather alert procedures;

(iii) Your procedures and thresholds for activating your ice and weather management system(s); and

(iv) Confirmation that you will operate ice and weather management and alert systems continuously throughout the planned operations, including mobilization and demobilization operations to and from the Arctic OCS.

(3) *Source control and containment equipment capabilities.* A general description of how you will comply with § 250.471 of this title.

(4) *Deployment of a relief well rig.* A general description of how you will comply with § 250.472 of this title, including a description of the relief well rig, the anticipated staging area of the relief well rig, an estimate of the time it would take for the relief well rig to arrive at the site of a loss of well control, how you would drill a relief well if necessary, and the approximate timeframe to complete relief well operations.

(5) *Resource-sharing.* Any agreements you have with third parties for the sharing of assets or the provision of mutual aid in the event of an oil spill or other emergency.

(6) *Anticipated end of seasonal operations dates.* Your projected end of season dates, and the information used to identify those dates, for:

(i) The completion of on-site operations, which is contingent upon your capability in terms of equipment and procedures to manage and mitigate risks associated with Arctic OCS conditions; and

(ii) The termination of drilling operations consistent with the relief rig planning requirements under § 250.472 of this title and with your estimated timeframe under paragraph (c)(4) of this section for completion of relief well operations.

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